US005697536C1

(12) REEXAMINATION CERTIFICATE (4794th)

United States Patent
Eggers et al.

(10) Number: US 5,697,536 C1
(45) Certificate Issued: Jun. 10, 2003

(54) SYSTEM AND METHOD FOR ELECTROSURGICAL CUTTING AND ABLATION

(75) Inventors: Philip E. Eggers, Dublin, OH (US); Hira V. Thapliyal, Los Altos, CA (US)

(73) Assignee: Arthrocare Corporation, Sunnyvale, CA (US)

Reexamination Request:
No. 90/005,601, Dec. 30, 1999

Reexamination Certificate for:
Patent No.: 5,697,536
Issued: Dec. 16, 1997
Appl. No.: 08/746,800
Filed: Nov. 18, 1996

Related U.S. Application Data

(60) Division of application No. 08/485,219, filed on Jun. 7, 1995, which is a continuation-in-part of application No. 08/446,767, filed on Jun. 2, 1995, which is a continuation-in-part of application No. 08/059,681, filed on May 10, 1993, now abandoned, which is a continuation-in-part of application No. 07/958,977, filed on Oct. 9, 1992, now Pat. No. 5,366,443, which is a continuation-in-part of application No. 07/817,575, filed on Jan. 7, 1992, now abandoned.

(51) Int. Cl.[7] A61M 37/00
(52) U.S. Cl. 604/114; 604/22
(58) Field of Search 604/22, 43, 48, 604/113, 114, 264, 271; 606/27–31, 32–49

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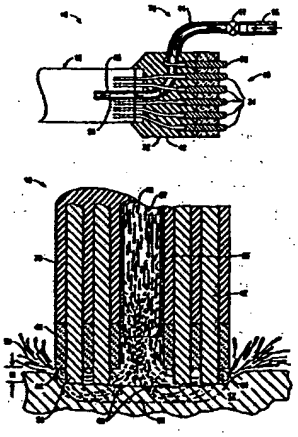
Primary Examiner—Manuel Mendez

(57) ABSTRACT

An electrosurgical probe (10) comprises a shaft (13) having an electrode array (12) at its distal end and a connector (19) at its proximal end for coupling the electrode array to a high frequency power supply (28). The shaft includes a return electrode (55, 56) recessed from its distal end and enclosed within an insulating jacket (18). The return electrode defines an inner passage (83) electrically connected to both the return electrode and the electrode array for passage of an electrically conducting liquid (50). By applying high frequency voltage to the electrode array and the return electrode, the electrically conducting liquid generates a current flow path between the target site and the return electrode so that target tissue may be cut or ablated. The probe is particularly useful in dry environments, such as the mouth or abdominal cavity, because the electrically conducting liquid provides the necessary return current path between the return electrode and the target site.



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L. Malis *New Trends in Microsurgery and Applied Technology* (pp. 9–16).

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"Valley Forge's new products" *Clinica* vol. 475, p. 5 (1991).

The MALIS Bipolar Electrosurgical Systems CMC–II (Catalog 80–1170) 14 pgs.

REEXAMINATION CERTIFICATE ISSUED UNDER 35 U.S.C. 307

NO AMENDMENTS HAVE BEEN MADE TO THE PATENT

AS A RESULT OF REEXAMINATION, IT HAS BEEN DETERMINED THAT:

The patentability of claims 1–64 is confirmed.

* * * * *

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: ASSISTANT COMMISSIONER FOR PATENTS
Washington, D.C. 20231

APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
90/005,601	DECEMBER 30, 1999	5,697,536	16238-00610

ARTHROCARE CORPORATION
680 VAQUEROS AVENUE
SUNNYVALE, CA 94085-3523

EXAMINER	
MENDEZ, M.	
ART UNIT	**PAPER**
3763	18

DATE MAILED: MARCH 14, 2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

cc: William C. Fuess, 3rd party attorney

Notice of Intent to Issue Ex Parte Reexamination C rtificate	C ntrol No. 90/005,601	Patent Under Reexamination	
	Examiner Manuel M ndez	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

1. ☒ Prosecution on the merits is (or remains) closed in this ex parte reexamination proceeding. This proceeding is subject to reopening at the initiative of the Office or upon petition. *Cf.* 37 CFR 1.313(a). A Certificate will be issued in view of

(a) ☒ Patent owner's communication(s) filed: *19 December 2002*.

(b) ☐ Patent owner's late response filed: _____.

(c) ☐ Patent owner's failure to file an appropriate response to the Office action mailed: _____.

(d) ☐ Patent owner's failure to timely file an Appeal Brief (37 CFR 1.192).

(e) ☐ Other: _____.

Status of *Ex Parte* Reexamination:

(f) Change in the Specification: ☐ Yes, ☐ No

(g) Change in the Drawing: ☐ Yes, ☐ No

(h) Status of the Claim(s):

(1) Patent claim(s) confirmed: *1-64*.

(2) Patent claim(s) amended (including dependent on amended claim(s)): _____.

(3) Patent claim(s) cancelled: _____.

(4) Newly presented claim(s) patentable: _____.

(5) Newly presented cancelled claims: _____.

2. ☒ Note the attached statement of reasons for patentability and/or confirmation. Any comments considered necessary by patent owner regarding reasons for patentability and/or confirmation must be submitted promptly to avoid processing delays. Such submission(s) should be labeled: "Comments On Statement of Reasons for Patentability and/or Confirmation."

3. ☐ Note attached NOTICE OF REFERENCES CITED (PTO-892).

4. ☒ Note attached LIST OF REFERENCES CITED (PTO-1449).

5. ☐ The drawing correction request filed on _____ is: ☐ approved ☐ disapproved.

6. ☐ Acknowledgment is made of the priority claim under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some* c)☐ None of the certified copies have

☐ been received.

☐ not been received.

☐ been filed in Application No. _____.

☐ been filed in reexamination Control No. _____.

☐ been received by the International Bureau in PCT Application No. _____.

* Certified copies not received: _____.

7. ☐ Note attached Examiner's Amendment.

8. ☐ Note attached Interview Summary (PTO-474)

9. ☐ Other: _____

Manuel Mendez
Primary Examiner
Art Unit: 3763

cc: Requester (if third party requester)

REEXAMINATION OF U.S. PATENT NUMBER 5,697,536

STATEMENT OF REASONS FOR PATENTABILITY AND/OR CONFIRMATION

The following is an examiner's statement of reasons for patentability and/or confirmation of the claims found patentable in this reexamination proceeding:

The examiner of record concurs with the arguments presented by the patent owner on paper number 15. Accordingly, it is concluded that claims 1-64 are allowable over the prior art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manuel Mendez whose telephone number is 703-308-2221. The examiner can normally be reached on 0730-1800 hrs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Brian Casler can be reached on 703-308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

Manuel Mendez
Primary Examiner
Art Unit 3763

March 4, 2003

ANGELA D. SYKES
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

FORM PTO-1449 (Modified) LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)	Attorney Docket No. 16238-000610	Patent No.: *5,697,536*
	Applicant: PHILIP E. EGGERS et al.	
	Issue Date: *December 16, 1997*	Group:

Reference Designation	U.S. PATENT DOCUMENTS					
Examiner Initial	Document No.	Date	Name	Class	Sub-class	Filing Date
___ AA						
___ AB						
___ AC						
___ AD						
___ AE						
___ AF						

FOREIGN PATENT DOCUMENTS						
						Translation (yes/no)
___ AG						
___ AH						
___ AI						

OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)	
___ AJ	Correspondence from C. Larson *Dept. of Health & Human Services* dated April 22, 1991 (3pgs)
___ AK	Summary of Safety and Effective Information (2pgs)
___ AL	Correspondence from R. Britain *Dept. of Health & Human Services* dated August 12, 1985
___ AM	Correspondence from J. Malis *Valley Forge* dated July 25, 1985 (3pgs)
___ AN	L. Malis *J. Neurosurg.* Vol. 85, pp. 970-975 (1996).
___ AO	Excerpt from seminar by L. Malis, MD *1995 American Assoc. of Neurologicla Surgeons Meeting* (1pg)
___ AP	L. Malis *The Value of Irrigation During Bipolar Coagulation* (1pg)
___ AQ	L. Malis *New Trends in Microsurgery and Applied Technology* (pgs 9-16)
___ AR	*Codman Bipolar Electrosurgery Products* brochure (8 pgs)
___ AS	*The MALIS Bipolar Coagulating and Bipolar Cutting System CMC-II* brochure (2pgs)
___ AT	"Valley Forge's new products" *Clinica* Vol. 475, p. 5 (1991)
___ AU	The MALIS Bipolar Electrosurgical Systems CMC-II (Catalog 80-1170) 14 pgs
EXAMINER [signature]	DATE CONSIDERED FEBRUARY 25, 2003

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

I hereby certify that this correspondence is being deposited with the United States Postal Service Express Mail Post Office to Addressee service under 37 CFR 1.10 on the date indicated below, Express Mail No. EU627186305 and is addressed to Assistant Commissioner for Patents, Washington, D.C. 20231

On December 19, 2002

By Katie Zarzana

PATENT

Attorney Docket No.: RE-EXAM – 1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: EGGERS et al.

Reexamination of U.S. Patent No.: 5,697,536
Reexamination No.: 90/005,601
Reexamination Filed: December 30, 1999

Patent Filed: November 18, 1996
Patent Issued: December 16, 1997

For: **SYSTEM AND METHOD FOR ELECTROSURGICAL CUTTING AND ABLATION**

Examiner: Manuel Mendez

Art Unit: 3763

RESPONSE TO FIRST OFFICE ACTION

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

This is in response to the Office Action mailed November 15, 2002, for which a response is due January 15, 2003. Thus, this response is timely filed.

REMARKS

35 U.S.C. §102

The Office Action rejected claims 1-64 under 35 U.S.C. §102(b) as being anticipated by numerous references. Patentee traverses and addresses each rejection as follows.

In making various rejections, instead of providing separate comments, the Office Action appears to have incorporated a Supplemental Invalidity Response ("SIR") that Smith & Nephew served on ArthroCare on June 9, 2002 in the case entitled *ArthroCare*

Corp. v. Smith & Nephew, Inc., C.A. No. 01-504-SLR ("Smith & Nephew litigation"). In the Smith & Nephew litigation, ArthroCare has accused Smith & Nephew of infringing three of Patentee's patents, including U.S. Patent No. 5,697,536 ("'536 patent"). The SIR was previously submitted by Patentee in an IDS dated June 19, 2002. Accordingly, Patentee will address the arguments made in the SIR by direct reference to the SIR.

Patentee notes that although the Office Action rejects claims 1-64 of the '536 patent, the SIR only provided a discussion of claim 45. As such, even if the Office Action and SIR provided a basis for rejecting claim 45, which they do not, there is no basis for rejecting any other claim of the '536 patent. In view of this deficiency, and in view of the large number of references found in the SIR, Patentee will address the core deficiencies in the references primarily as they relate to claim 45.

Patentee is also submitting with this response an IDS containing additional materials submitted by the defendant in the Smith & Nephew litigation. To expedite prosecution, Patentee discusses the subject matter of this IDS below.

U.S. Patent No. 3,815,604 to O'Malley (Reference 3 in the SIR)

The SIR, citing to col. 9, lines 9-25 of O'Malley, asserts that O'Malley teaches an "electrically conducting fluid [which] generates a current flow path between [a] return electrode and [an] electrode terminal."

Patentee disagrees. O'Malley appears to disclose a monopolar device in which the return electrode is attached to the outside of the patient's body. O'Malley does not disclose that this return electrode is in contact with an electrically conducting fluid. Thus, O'Malley does not disclose an electrically conducting fluid which generates a current flow path between a return electrode and an electrode terminal.

Moreover, it is not clear that the disclosure of saline "or other liquid" at col. 9, lines 9-25 is made in reference to the RF embodiment as opposed to the other, non-RF embodiments, in the O'Malley reference. O'Malley does not disclose that the function of the saline "or other liquid" is to generate a current flow path between any two electrodes much less between an electrode terminal and a return electrode. Instead, O'Malley discloses that the saline "or other liquid" is used to: i) feed solution into the patient's eye

as material is removed from the eye via a discrete treatment device, and ii) maintain a predetermined pressure.

Quite simply, Patentee is unable to find any teaching or suggestion whatsoever in O'Malley regarding the use of electrically conductive fluid to generate a current flow path between a return electrode and an electrode terminal. Based upon these reasons alone, O'Malley fails to anticipate any claims of the '536 patent.

Accordingly, Patentee requests withdrawal of this rejection.

U.S. Patent No. 3,939,839 to Curtiss (Reference 9 in the SIR)

The SIR, citing to col. 2, lines 40-63 of Curtiss, asserts that Curtiss teaches an "electrically conducting fluid [which] generates a current flow path between [a] return electrode and [an] electrode terminal."

Patentee disagrees. Curtiss discloses a monopolar device in which the return electrode, or "patient plate," is attached to the outside of the patient's body. Curtiss does not disclose that this return electrode is in contact with an electrically conducting fluid. Thus, Curtiss does not disclose an electrically conducting fluid which generates a current flow path between a return electrode and an electrode terminal.

In addition, Patentee is unable to find any teaching or suggestion in Curtiss of an electrically conducting fluid, even though the SIR claims that an electrically conductive fluid is disclosed at col. 2, lines 40-63. Instead, Patentee notes that Curtiss discloses only "irrigation fluid" which is used to achieve one object of the invention in Curtiss, namely, "maintain[ing] a clearer visual field in front of the telescope and permit[ing] longer periods of uninterrupted operation of the instrument than heretofore." (Curtiss, col. 2, lines 12-16). Curtiss never states or suggests that the irrigation fluid is electrically conductive or provides a current flow path between a return electrode and an electrode terminal.

Accordingly, Patentee requests withdrawal of this rejection.

Piercey et al., Gastroenterology, Vol. 74, No. 3, 527-534 (Reference 12 in the SIR)

The SIR, citing to page 529 of Piercey, asserts that Piercey teaches an "electrically conducting fluid [which] generates a current flow path between [a] return electrode and [an] electrode terminal."

Patentee disagrees. Piercey discloses a monopolar device in which the return electrode, or "ground plate," is attached to the outside of the patient's body. (Piercey at S&N 0011315, Fig. 2). Piercey does not disclose that this return electrode is in contact with an electrically conducting fluid. Thus, Piercey does not disclose an electrically conducting fluid which generates a current flow path between a return electrode and an electrode terminal.

Accordingly, Patentee requests withdrawal of this rejection.

Dennis et al., Digestive Diseases and Sciences, Vol. 24, No. 11, 845-848 (Reference 16 in the SIR)

The SIR, citing to page 846 of Dennis, asserts that Dennis teaches an "electrically conducting fluid [which] generates a current flow path between [a] return electrode and [an] electrode terminal."

Patentee disagrees. Dennis discloses a monopolar device in which the return electrode is attached to the outside of the patient's body in the form of a ground plate. (Dennis at S&N 0011338, Fig. 1). Dennis does not disclose that this return electrode is in contact with an electrically conducting fluid. Thus, Dennis does not disclose an electrically conducting fluid which generates a current flow path between a return electrode and an electrode terminal.

Accordingly, Patentee requests withdrawal of this rejection.

Barry et al., CRC Press, American Heart Journal Vol. 117, 332-341 (Reference 21 in the SIR)

The SIR, citing to page 334 of Barry, asserts that Barry teaches an "electrically conducting fluid [which] generates a current flow path between [a] return electrode and [an] electrode terminal."

Patentee disagrees. Barry discloses two devices: a forceps embodiment and an angioplasty balloon. In the forceps embodiment, the "vessel segment was perfused with saline or autologous heparinized canine blood until completely flushed through." (Barry at 334). Then, "a small section of the artery was compressed between the electrode plates" and "RF energy was applied at the desired level." (*Id.*) The description of the forceps embodiment in Barry does not teach an electrically conductive fluid that generates a current flow path between a return electrode and an electrode terminal because neither electrode is in contact with the electrically conducting fluid. Instead, both electrodes are in contact with the outside of the vessel.

In the angioplasty balloon embodiment, Barry discloses inflating the balloon which causes the electrodes to come into contact with the outer wall of the blood vessel. Instead of generating a current flow path through an electrically conducting fluid, Barry describes "passing current through the electrical resistance of the tissue lying immediately adjacent to the electrodes." As such, Barry fails to disclose generating a current flow path between a return electrode and an electrode terminal.

In addition, none of the embodiments in the Barry article discloses a return electrode. In each device, each electrode appears to have the same or similar current density as the other and each electrode is designed to cause a tissue effect. Barry fails to disclose an electrode that has lower current density than the other or that is designed not to cause a tissue effect.

In contrast, all of the claims of the '536 patent require an electrode terminal (which the specification defines as an active electrode) and a return electrode. It is well established that the term "return electrode" means an electrode with a lower current density than the active electrode and which is not designed to have a tissue effect. Even

one of the references cited in the SIR (Number 54 Kramolowsky et al. *Journal of Urology Vol. 146, p669*, right hand column) and previously considered by the Examiner, recognizes that an "important concept in electrosurgery" is that the return electrode has a lower current density than the active electrode and is not designed to have a tissue effect.

Accordingly, Patentee requests withdrawal of this rejection.

Swain et al., Gut, 25, 1424-1431 (Reference 24 in the SIR)

The SIR, citing to page 1425 of Swain, asserts that Swain teaches an "electrically conducting fluid [which] generates a current flow path between [a] return electrode and [an] electrode terminal."

Patentee disagrees. On page 1425, Swain discusses four devices. One of the devices, the "heater probe," is not relevant because it works by heating and not by applying electrical current to tissue. Of the remaining embodiments, two are "monopolar" and one is "bipolar".

With respect to the monopolar embodiments, Swain discusses "a conducive interfacial film of liquid between the monopolar electrode and the tissue." In a monopolar device, however, the return electrode is attached to the outside of the patient's body in the form of a grounding plate. Swain's discussion of the monopolar embodiments does not disclose that the return electrode is in contact with an electrically conducting fluid. As such, Swain does not teach the use of an electrically conducting fluid which generates a current flow path between a return electrode and an electrode terminal.

Swain also discloses a "bipolar probe" "where current passes through a small area of tissue between two or more electrodes." (Swain at 1425). The electrodes in the bipolar probe are in "a pattern that allow[s] at least two electrodes to be in contact with tissue, at whatever angle the probe [is] applied" and, as a result, the current passes through the tissue, not the electrically conducting fluid. (*Id.*). Thus, Swain does not teach an electrically conducting fluid which generates a current flow path between the return electrode and the electrode terminal.

In addition, regarding the bi-polar probe, Swain teaches the use of two or more active electrodes because each electrode appears to have the same or similar current density and each electrode is designed to cause a tissue effect. As a result, Swain clearly fails to disclose a return electrode as required by patentee's claims.

Accordingly, Patentee request withdrawal of this rejection.

U.S. Patent No. 4,590,934 to Malis (Reference 28 in the SIR)

The SIR, citing to col. 2, line 18 of Malis, asserts that Malis teaches an "electrically conducting fluid [which] generates a current flow path between [a] return electrode and [an] electrode terminal."

Patentee disagrees. The Malis patent primarily discusses a generator and contains no drawings of the forceps disclosed. It is clear, however, that both electrodes of the forceps in Malis are in contact with the tissue and that, as a result, an electrically conducting fluid does not create a current flow path between any two electrodes, much less a return electrode and an electrode terminal. In fact, the Malis patent teaches away from the creation of a current flow path through an electrically conducting fluid when it states:

> if the forceps blades are virtually parallel and are deeply immersed in saline, there can be major shunting of current through the saline, despite isolation of the power output. But if the forceps blades are bowed or angled so that the tips almost meet while the parallel portion of the blades remain well separated, current flow is restricted to the zone between the tips with little shunting through the saline." (Malis, col. 1, line 66 to col. 2, line 6).

As such, Malis does not disclose an electrically conducting fluid generating a current flow path between an active and return electrode.

In addition, the forceps disclosed by Malis do not have a return electrode. Instead, Malis teaches the use of two active electrodes (the tips of the forceps). There is no suggestion in Malis that either electrode has a lower current density than the other or is not designed to have a tissue effect.

Accordingly, Patentee disagrees that Malis anticipates any of claims 1-64, and request withdrawal of this rejection.

U.S. Patent No. 4,805,616 to Pao (Reference 36 in the SIR)

The SIR, citing to col. 7, lines 30-32 of Pao, asserts that Pao teaches an "electrically conducting fluid [which] generates a current flow path between [a] return electrode and [an] electrode terminal."

Patentee disagrees. For convenience, Patentee reproduces the section of Pao apparently cited by the SIR, starting with col. 7, line 27 and ending at line 37:

> The preferred use of the device is in the performing of anterior capsulotomies. In that procedure, a limbal incision is made and the active tip 32 inserted between the anterior capsule and the corneal endothelium. Preferably the anterior capsule surface is wetted with the conventional sterile salt solution. The two electrodes in the active tip of the probe are placed in contact with the anterior capsule surface and a suitable current passed for a length of time sufficient to coagulate a small area of the capsule immediately beneath the active tip. (emphasis added).

It is evident that Pao teaches placing both electrodes in contact with the tissue surface so that a suitable current passes through the tissue, and not through an electrically conducting fluid, to coagulate the capsule beneath the tip. Accordingly, Pao fails to disclose an electrically conducting fluid which generates a current flow path between an active electrode and a return electrode.

Furthermore, Patentee notes that the Pao patent is a continuation-in-part of U.S. Patent 4,674,499 to Pao ('499) and incorporates the '499 patent by reference. The '499 patent teaches the use of fluid "to wash away blood and other fluid and coagulation by-products simultaneous with cautery." (e.g., see '499 col. 9, lines 42-47.) Patentee notes that the '499 patent was considered in the prosecution of the '536 patent.

As such, Patentee disagrees that Pao anticipates any of claims 1-64, and request withdrawal of this rejection.

Tucker et al., Journal of Urology, Vol. 141, 662-665 (Reference 37 in the SIR)

The SIR, citing to page 663 of Tucker, asserts that Tucker teaches an "electrically conducting fluid [which] generates a current flow path between [a] return electrode and [an] electrode terminal."

Patentee disagrees. On page 663 (in the right hand column), which is the portion of the reference identified in the SIR as disclosing an electrically conducting fluid which generates a current flow path, Tucker discusses an experiment using various probes where "each probe was held in contact with the liver . . . by a test jig which assured that the contact pressure and electrode-tissue area was constant . . . ." This teaches putting each electrode in contact with tissue to pass current through tissue in order to treat the tissue.

Patentee notes that on page 664, (in the right hand column) Tucker states that, with their bipolar device, "in saline, some of the current flows from electrode to electrode without passing through the tissue, but a significant part of the total current flows through the low resistance tissue to cause burns." Patentee notes, however, that Tucker explicitly states that a "significant part" of the total current actually flows through the tissue to effectuate treatment. The mention of some current flowing between electrodes is not relevant because Tucker teaches that it is the "significant part of the total current" which "flows through the tissue" that causes the tissue effect and not any current that "flows from electrode to electrode without passing through tissue." (Tucker at 664). Clearly, by teaching that the electrodes must be in contact with the tissue and that it is the current flow through the tissue which is relevant, Tucker does not anticipate the claimed inventions.

In addition to the deficiencies discussed above, Tucker also fails to disclose a return electrode. Instead, Tucker teaches the use of multiple active electrodes. Both electrodes are designed to cause a tissue effect, and there is no suggestion that one electrode has a lower current density than the other electrode.

Accordingly, Patentee disagrees that Tucker anticipates any of claims 1-64, and requests withdrawal of this rejection.

Lee et al., JACC, Vol. 13, No. 5, 1167-75 (Reference 38 in the SIR)

The SIR, citing to page 1168 of Lee, asserts that Lee teaches an "electrically conducting fluid [which] generates a current flow path between [a] return electrode and [an] electrode terminal."

Patentee disagrees. In each of the four experiments conducted by Lee, the electrodes were in contact with the tissue: "for these studies, radiofrequency energy was delivered from the tip of the electrode catheter through tissue samples to a copper electrode plate." (Lee, page 1168). Thus, Lee fails to disclose an electrically conducting fluid which generates a current flow path between a return electrode and an electrode terminal. If there were such a current flow path, the electrodes would not need to be in contact with the tissue.

Although it is not clear, it appears that this reference may disclose two bipolar experiments. In the case of the vascular fusion study, the electrodes were placed in contact with tissue and a drop of blood was placed between the tissue. The electrodes appear to be identical. Thus, there can be no return because neither electrode is described as having a lower current density than the other and there is no teaching or suggestion that only *one* electrode produces a tissue effect. In addition, there is no disclosure of a current flow path through an electrically conductive fluid between an electrode terminal and a return electrode because the electrodes are placed in contact with the tissue.

In the case of the angioplasty balloon catheter, the article states that the catheter was inserted into an arterial segment and then the segment and tip were placed in a beaker of blood. This does not mean that the catheter was in contact with the blood. As such, this embodiment fails to disclose an electrically conducting fluid which generates a current flow path between an electrode terminal and a return electrode. Moreover, in the case of the angioplasty balloon, the article does not disclose a return electrode. The electrodes appear to be identical, and there is no disclosure that either electrode has a lower current density than the other or that either electrode is designed not to have a tissue effect.

Accordingly, Patentee disagrees that Lee anticipates any of claims 1-64, and requests withdrawal of this rejection.

WO 90/03152 to Considine et al. (Reference 43 in the SIR)

The SIR, citing to page 11 of Considine, asserts that Considine teaches an "electrically conducting fluid [which] generates a current flow path between [a] return electrode and [an] electrode terminal."

Patentee disagrees. Considine does not disclose an electrically conducting fluid. In addition, there is no disclosure of an active or return electrode. Instead, it appears that this device operates by cutting with resistive heating at the tip of the probe and not by the use of an electrically conducting fluid which generates a current flow path between the return electrode and the electrode terminal. Patentee submits that Considine clearly teaches cutting tissue by the use of heat.

Accordingly, Patentee disagrees that Considine anticipates any of claims 1-64, and requests withdrawal of this rejection.

U.S. Patent No. 4,936,281 to Stasz (Reference 46 in the SIR)

The SIR, citing to col. 6, line 42 of Stasz, asserts that Stasz teaches an "electrically conducting fluid [which] generates a current flow path between [a] return electrode and [an] electrode terminal."

Patentee disagrees. Stasz discloses a device in which both electrodes are in contact with the tissue. As Stasz states at col. 3, line 65 to col. 4, line 2:

> Each of the backup plate 32, the piezoelectric transducer means 30 and the RF cutter means 28 is provided with a pair of longitudinal bores 44 and 46 which are aligned with one another permitting electrical conductors 48 and 50 coming from the proximal connector 18 to reach and connect to the distal tip bipolar electrodes 38 and 40. In this manner, rf energy from the signal generator 24 can be impressed across the bipolar electrodes 38 and 40 to create a high intensity current path therebetween for performing RF ablation of the tissue coming in contact with the distal end of the tip member 28.

Thus, Stasz fails to disclose an electrically conducting fluid which generates a current flow path between a return electrode and an electrode terminal. If there were such a current flow path, the electrodes would not need to be in contact with the tissue.

In addition, Stasz does not disclose a return electrode. Instead, Stasz teaches the use of two active electrodes. Both electrodes are similar in size and current density, and both are intended to have a tissue effect.

Accordingly, Patentee disagrees that Stasz anticipates any of claims 1-64, and requests withdrawal of this rejection.

U.S. Patent No. 5,009,656 to Reimels (Reference 52 in the SIR)

The Reimels patent was cited in the prosecution of the '536 patent and is not proper subject matter for this Reexamination.

In any event, Reimels does not disclose the claimed inventions. The SIR, citing to col. 2, line 26 of Reimels, asserts that Reimels teaches an "electrically conducting fluid [which] generates a current flow path between [a] return electrode and [an] electrode terminal." Patentee disagrees.

For convenience, Patentee provides the text of col. 4, lines 3-18, below:

> When sufficient power is applied across electrodes 22, 24, a series of sparks are produced between the electrodes across cavity 30. Applicant has found that the initiation of the spark produces sufficient energy to dispel fluids (such as normal saline solution used to irrigate the knee joint) from between electrodes 22, 24. That is, despite the presence of electrically conductive saline at the surgical site, an air gap is essentially created within cavity 30 which more easily maintains sparking. In fact, even with tips 22a, 24a in contact with tissue, the air gap permits continuous sparking which cuts or smoothes the tissue, or permits coagulation, instead of destroying the tissue. This is because current flows across the air gap rather than through the tissue (as is the case where insulation 25 is coextensive with tips 22a, 24a).

Contrary to the assertion found in the SIR, Reimels teaches a device that *dispels* an electrically conducting fluid from between the electrodes. The current then passes through an air-gap. Air is not an electrically conducting fluid. Thus, Reimels fails to disclose an electrically conducting fluid which generates a current flow path between a return electrode and an electrode terminal.

Accordingly, Patentee disagrees that Reimels anticipates any of claims 1-64, and requests withdrawal of this rejection.

Olsen, Bipolar Laparoscopic Cholecystectomy Lecture, (Reference 57 in the SIR)

The SIR, citing to page 6 of Olsen, asserts that Olsen teaches an "electrically conducting fluid [which] generates a current flow path between [a] return electrode and [an] electrode terminal."

Patentee disagrees. Patentee is unable to find any reference in Olsen to a return electrode. Olsen does not state that one of the electrodes has a lower current density than the other or that one of the electrodes is designed not to have a tissue effect. As such, Olsen fails to disclose a return electrode.

Moreover, while Olsen recites on page 6 that saline may be used "to enhance current flow at the tip of the device," Patentee is unable to find any disclosure in Olsen which teaches that the saline forms a conductive path between the electrodes. Rather, Olsen makes clear on page 8 that the saline is used to enhance current flow at the distal tip by removing charred tissue or coagulum, which are both resistive, from the distal tip. This is clear from the videotape of which reference 57 in the SIR is a transcription, and which Patentee can provide to the Examiners if they request it.

Accordingly, Patentee disagrees that Olsen anticipates any of claims 1-64, and requests withdrawal of this rejection.

U.S. Patent No. 5,167,659 to Ohtomo et al. (Reference 66 in the SIR)

The SIR, citing to col. 2, line 10 of Ohtomo, asserts that Ohtomo teaches an "electrically conducting fluid [which] generates a current flow path between [a] return electrode and [an] electrode terminal."

Patentee disagrees. Ohtomo discloses a monopolar device in which the return electrode is attached to the outside of the patient's body in the form of a "counter electrode plate." (Ohtomo at col. 3, lines 16-20). Ohtomo does not disclose that this return electrode is in contact with an electrically conducting fluid. Thus, Ohtomo does

not disclose an electrically conducting fluid which generates a current flow path between a return electrode and an electrode terminal.

Accordingly, Patentee disagrees that Ohtomo anticipates any of claims 1-64, and requests withdrawal of this rejection.

U.S. Patent No. 5,171,311 to Rydell et al. (Reference 67 in the SIR)

The SIR, citing to col. 4, line 10, asserts that Rydell teaches an "electrically conducting fluid [which] generates a current flow path between [a] return electrode and [an] electrode terminal."

Patentee disagrees. Rydell discloses contacting the electrodes with the tissue in order to cut. Rydell teaches that the current flows through the tissue, not through an electrically conducting fluid. (Rydel at col. 4, line 15-21 and col. 4, line 59 to col. 5, line 3). Thus, Rydell fails to disclose an electrically conducting fluid which generates a current flow path between a return electrode and an electrode terminal. If there were such a current flow path, the electrodes would not need to be in contact with the tissue.

Although Rydell discloses the use of saline as a flushing liquid, Rydell does not describe the saline as generating a current flow path between the return electrode and the electrode terminal. For convenience, Patentee provides the text of col. 4, lines 4-11 of Rydell below:

> A tube 54 is secured to the distal end of the barb coupler 52 and that tube 54 extends through the bore 38 and the lumen 18, reaching the distal port 28 in the plug 20. The barb coupler 52 is adapted to be coupled to a further tube (not shown) leading to a source of flushing liquid, e.g., saline, which allows the flushing liquid to be perfused through the instrument and out its distal port 28.

Contrary to the assertion of the SIR, the cited section of Rydell merely teaches that the device may be coupled to a source of flushing liquid. There is no mention of the liquid being used to provide a current flow path between electrodes.

Furthermore, Rydell goes on to teach that "[w]hen blood or other body fluids obscure the laparoscopic view of the surgical site, a flushing liquid can be injected through the coupler 52 and through the tube 54 to exit the port 28 while a vacuum is applied, via barbed coupler 50, to allow the flushing liquid and blood to be removed."

(see col. 4, lines 26.) Clearly, Rydell teaches that the flushing liquid is used for irrigation of the site rather than creation of any current flow paths between electrodes.

In addition, Rydell does not disclose that either electrode has a lower current density than the other or that either electrode is designed not to cause a tissue effect. Thus, Rydell fails to disclose a return electrode.

Accordingly, Patentee disagrees that Rydell anticipates any of claims 1-64, and requests withdrawal of this rejection.

U.S. Patent No. 5,217,459 to Kamerling (Reference 70 in the SIR)

The SIR, citing to col. 3, line 1 of Kamerling, asserts that Kamerling teaches an "electrically conducting fluid [which] generates a current flow path between [a] return electrode and [an] electrode terminal."

Patentee disagrees. Kamerling discloses placing the electrodes in contact with tissue in order to effect cutting. (Kammerling col. 2:43-46). Kamerling teaches that current flows through tissue, not through an electrically conducting fluid. Thus, Kamerling fails to disclose an electrically conducting fluid which generates a current flow path between a return electrode and an electrode terminal. If there were such a current flow path, the electrodes would not need to be in contact with the tissue.

Although Kamerling does discuss saline, the use of saline in Kamerling is to increase the conductivity of the tissue, not to create a current flow path. For convenience, Patentee provides the text of col. 2, line 67 through col. 3, line 2 of Kamerling below:

> The annular space between member 52 and housing 14 comprises a conduit 56 through which an irrigating solution, preferably comprising saline, can be conducted to the surface of the tissue adjacent the distal ends of the electrodes 22 and 26 to assist in increasing the conductivity of the tissue in the area where cutting is to take place while at the same time providing a cooling bath for the surrounding tissue so that likelihood of burning or other damage as a result of the applied current will be minimized.

As such, Kamerling teaches the use of the fluid to increase the conductivity of the tissue so that the current flows more effectively between the electrodes through the tissue, as opposed to through the electrically conducting fluid itself.

Accordingly, Patentee disagrees that Kamerling anticipates any of claims 1-64, and requests withdrawal of this rejection.

35 U.S.C. §103

35 U.S.C. §103

The Office Action rejected claims 1-64 under 35 U.S.C. §103(a) as being unpatentable over any one or more of references 1, 4, 5, 6, 7, 10, 11, 13, 17, 30, 33, 40, 44, 50, 55, 56, 61, 69, 71, 72, 73 in view of any one or more of references 3, 9, 12, 16, 21, 24, 28, 36, 37, 38, 43, 46, 52, 57, 66, 67, 70, claiming that all modifications to the base references following the teachings of the secondary references are considered obvious design choices.

The Office Action rejected claims 1-64 under 35 U.S.C. §103(a) as being unpatentable over any one or more of 2, 34, and 47 in view of any one or more of references 3, 9, 12, 16, 21, 24, 28, 36, 37, 38, 43, 46, 52, 57, 66, 67, 70, claiming that all modifications to the base references following the teachings of the secondary references, are considered obvious design choices.

The Office Action rejected claims 1-64 under 35 U.S.C. §103(a) as being unpatentable over reference 59 (U.S. Patent No. 5,084,044 to Quint) in view of any one or more of references 3, 9, 12, 16, 21, 24, 28, 36, 37, 38, 43, 46, 52, 57, 66, 67, 70 claiming that all modifications to the base references following the teachings of the secondary references are considered obvious design choices.

Patentee disagrees with all of the above stated 35 U.S.C. §103 rejections. First, as discussed below, the Office Action (incorporating the allegations made in the SIR) fails to establish a proper *prima facie* case of obviousness with regard to any and all of the rejections. Second, although the Office Action (i.e., the SIR) fails to establish any *prima facie* case, Patentee submits herewith an affidavit detailing significant objective evidence that Patentee's claims would not have been obvious under 35 U.S.C. §103.

Office Action Fails to Establish a *Prima facie* Case

It is well established that an Office Action must establish a *prima facie* case of obviousness in order to reject claims under 35 U.S.C. §103. This requires: 1) that the references used to assert obviousness teach or suggest all of the claim limitations; 2) there is some suggestion or motivation to modify the references or to combine the references; 3) the claimed subject matter be obvious in light of the prior art as a whole; (4) the modifications must not render the cited art unsatisfactory for its intended purpose or change the principle of operation of a device described in the cited art; and (5) a reasonable predictability that the combination or modification would successfully produce the desired characteristics.

First, to establish a proper *prima facie* case of obviousness, all claim limitations must be taught or suggested by the cited art. As discussed more thoroughly above with respect to the §102 rejections, Patentee clearly established that references 3, 9, 12, 16, 21, 24, 28, 36, 37, 38, 43, 46, 52, 57, 66, 67, 70 and 73 fail to teach one or more claim limitations. One of the most fundamental deficiencies of these references is that they fail to teach or suggest the use of an electrically conductive fluid to generate a current flow path between a return electrode and an electrode terminal. Moreover, none of the references that disclose at least two electrodes and electrically conducting fluid disclose a return electrode, that is, an electrode that has lower current density than an active electrode and that is designed not to have a tissue effect. Furthermore, the base references cited by the Office Action, namely 1, 2, 4, 5, 6, 7, 10, 11, 13, 17, 30, 33, 34, 40, 44, 47, 49, 50, 55, 56, 61, 69, 71, 72, and 73, do not cure these fatal deficiencies. As such, a *prima facie* case of obviousness *cannot* be established.

Second, regarding any suggestion or motivation to combine or modify the references, the SIR states that "each reference is directed to the same problem – applying electrical energy to a target site on a patient's body structure." This statement does not establish any actual motivation to combine or modify the references. It is well established that the fact that references can be combined or modified is not sufficient to establish a *prima facie* case of obviousness unless the prior art also suggests the desirability of the combination. Among the other weaknesses in the stated motivation to

combine is the fact that it suggests that there is a motivation to combine any one of the thousands of references disclosing an electrosurgical device with any one of the thousands of other references disclosing an electrosurgical device. As a matter of law, this cannot be sufficient to establish a motivation to combine. Patentee submits that the SIR fails to cite to any motivation to combine the references because neither the references, nor the knowledge of those skilled in the art at the time of the invention, contained any such motivation.

Similarly, the Office Action's statements that the proposed modifications are considered obvious design choices is insufficient to establish any suggestion or motivation to combine. The fact that each limitation in a claimed invention seperately may have been within the knowledge or capabilities of one of ordinary skill in the art is not sufficient without some objective reason to combine the teachings because the mere *ability* to combine the references does not constitute a *motivation* to do so. Again, Patentee submits that no objective reason is cited because none existed. Patentee also notes that any combination or modification based upon hindsight given the benefit of Patentee's own disclosure is impermissible.

Third, if the teachings of the cited references conflict, the Office Action must weigh the suggestive power of each reference in light of all of the prior art as a whole. Patentee notes that numerous references in the cited art require that electrodes contact tissue in order to conduct current therebetween. Such teachings clearly contradict the use of an electrically conducting fluid to generate a current flow path rather than the tissue generating such a current flow path. Accordingly, the art cited by the Office Action and the SIR actually teaches away from Patentee's claims and, thus, the prior art taken as a whole does not suggest the combination advocated in the SIR.

Fourth, it is well established that proposed modifications cannot render the cited art unsatisfactory for its intended purpose nor can the modifications change the principle of operation of a reference. Patentee believes that the modifications proposed by the Office Action render the cited references unsatisfactory for their intended purpose. Patentee finds that the intended purpose of all of the references is to pass current between electrodes through tissue. Any suggested modification to a device designed to pass

current through tissue to a device designed to pass current through an electrically conductive fluid clearly changes the operation of such a device. In addition, many of the references do not disclose a return electrode, that is, an electrode that has a lower current density than an active electrode and which is not designed to have a tissue effect. As such, any suggested modification of a device with electrodes designed to cause a tissue effect and to have high current densities to a device with an electrode not designed to have a tissue effect and with low current densities would change the principle of operation of such a device.

Finally, regarding the requirement of a reasonable expectation of success, Patentee believes that the cited references all contain implicit or explicit teachings to pass current between electrodes primarily through tissue. In view of these overwhelming teachings, Patentee is unable to determine what basis is being offered as to any reasonable expectation of success in making the proposed combinations or modifications. Clearly, the Office Action and the SIR do not offer any such reasoning as to why, at the time of Patentee's invention, there was a reasonable expectation of success in making any of the proposed modifications or combinations.

Objective Evidence of Non-Obviousness

To reiterate, although the Office Action fails to establish any *prima facie* case of obviousness, and Patentee is under no obligation to do so, Patentee submits herewith an affidavit under 37 C.F.R. §1.132 as objective evidence of non-obviousness of claims 1-64.

Based upon the above, Patentee requests withdrawal of the 35 U.S.C. §103(a) rejections of claims 1-64.

SUBMISSION OF INFORMATION DISCLOSURE STATMENT

Description of IDS References

Patentee submits an IDS herewith which includes documents recently served on ArthroCare in the *Smith & Nephew* litigation.

First, Patentee submits a group of documents including a letter dated September 10, 2002 from Smith & Nephew's attorneys and Exhibits A, B, and E thereto. (Exhibits C and D relate to other patents-in-suit which are not the subject of this reexamination and therefore are not included). These documents supplement Smith & Nephew's June 3, 2002 invalidity contentions (which were submitted with Patentee's June 19, 2002 IDS) in that they set forth Smith & Nephew's contentions as to why the dependant claims of the '536 patent are invalid.

Exhibit A is a listing of 15 references on which Smith & Nephew states that it intends to rely primarily in the above mentioned lawsuit (all of which have already been submitted by Patentee.) Exhibit B is a chart of the references (the reference numbers corresponding to the previously submitted SIR) as applied to the dependent claims at issue in the litigation. Exhibit E is a chart containing Smith & Nephew's obviousness arguments as applied to the claims at issue in the litigation.

Second, Patentee submits a group of documents including a letter dated October 9, 2002 from Smith & Nephew's attorneys and Exhibits A, B, and E thereto. (Exhibits C and D relate to other patents-in-suit which are not the subject of this reexamination and therefore are not included). Exhibit A is the most recent listing of 16 references on which Smith & Nephew states that it intends to rely primarily in the above mentioned lawsuit (the first fifteen references were previously submitted by Patentee and the additional reference, number 74, is submitted herewith and discussed below). Exhibit B is a chart of the references (the reference numbers corresponding to the previously submitted SIR) as applied to the dependent claims at issue in the litigation. Exhibit E is a chart containing Smith & Nephew's obviousness arguments as applied to the claims at issue in the

litigation. Exhibits B and E appear to be revised to include the newly cited reference number 74.

Third, Patentee submits a copy of the file history for U.S. Patent No. 4,116,198 to Roos. Although the Examiner previously concluded that Roos does not anticipate or render obvious any of the independent claims, the Patentee notes that the Roos file history was cited in the SIR (see reference number 15). Accordingly, Patentee wishes to place this file history in the record. As discussed below, Patentee submits that the Roos file history does not support a change in the Examiner's determination as to the Roos reference.

Discussion of Reference 74 – Malis Documents

Patentee submits reference 74, numbered SN61160 to SN61192, ("Malis documents") for consideration. Smith & Nephew cited these documents to Patentee for the first time on October 9, 2002 in its Supplemental Invalidity Contentions filed on that date. (*See* Exhibit A, page 2 and Exhibit B, page 21-22).

Many of the brochures and papers included among the Malis documents are undated or dated after the effective filing date of the '536 patent and, as a result, are not prior art. In any event, the Malis documents fail to anticipate or render obvious any of the claims of the '536 patent.

First, the Malis documents fail to teach or suggest a return electrode as required by Patentee's claims. Instead, Malis teaches the use of two active electrodes (the tips of the forceps). Each electrode is active (and not a return) because each has similar current density to the other and both are designed to have a tissue effect. To the contrary, Malis teaches, on page SN61173, right-hand column, starting with the 3rd paragraph, that a first embodiment of the bipolar device contains "the finest tip forceps because adequate cutting depends on a high concentration of current at the point of the forceps to divide the tissue smoothly." In another embodiment, Malis describes a "bipolar forceps with loop tips," which also has identically sized electrodes. Thus, there is no discussion of a return electrode as required by Patentee's claims.

Second, Malis does not teach the use of an electrically conductive fluid to generate a current flow path between a return electrode and an electrode terminal. In all of the designs disclosed, the electrodes are designed to be in contact with the tissue. (SN61173). The documents teach that current flows between the electrodes through the tissue. Thus, the Malis documents fail to disclose an electrically conducting fluid which generates a current flow path between a return electrode and an electrode terminal. If there were such a current flow path, the electrodes would not need to be in contact with the tissue.

Turning to page SN61173, bottom of the left-hand column to the top of the right-hand column, Patentee notes that Malis mentions the use of saline to increase the conductivity of the tissue. Yet, this teaching makes clear that Malis does not suggest that the saline generates a current flow path between the return electrode and the electrode terminal. This is because the materials state that the current flows only between the forceps tips. As a result, there is no current "spread" into the saline. (SN61171, SN61178, and SN61179).

Patentee notes that the Malis documents fail to teach numerous other claim limitations as well. However, in view of the above deficiencies alone, the Malis documents fail to anticipate or render obvious Patentee's claims.

Discussion of Reference 15 – Roos File History

The file history of the Roos '198 patent does not disclose the use of electrically conductive fluid for at least the following reasons.

First, the liquid is described as "washing liquid (29)." August 11, 1977 Amendment at 7. The washing liquid is never described as saline or Ringer's Lactate. Nor does the file wrapper ever say that the fluid is an electrically conductive washing liquid. Instead, it states that the washing fluid "would conduct electrical current just as the tissue fluid and the tissue itself of the human body." Amendment at 7. Human tissue, of course, is not necessarily conductive; and relative to an electrically conductive fluid (such as saline), it is far more resistive.

Second, the file wrapper does not appear to disclose a current flow path between the treatment electrode (12) and the neutral electrode (13). At the bottom of page 7 and the top of page 8 of the August 11, 1997 amendment, the file wrapper states that there is "a well-defined current path between the cutting electrode 12 and the neutral electrode 11 through the washing (and tissue) fluid." This is not stating that there is a current flow path just through the washing liquid. At most, it is stating that the path consists of a combination of the washing liquid and the tissue. This is confirmed by the text of the '198 patent application itself, which states that "due to the current conduction through the tissue fluid and the tissue itself, a true resistor R is also conceivable parallel to the capacitor between neutral electrode 11 and treatment electrode 12." S&N36942 (emphasis added). In the '536 patent, there is at least some current that flows directly from the active electrode, through the electrically conductive fluid, to the return electrode without going through the tissue.

Third, just because there is some current flow through a liquid does not mean that the liquid is an electrically conducting fluid. All liquids -- even distilled water -- will conduct some amount of current if the voltage is sufficiently high. Yet distilled water is considered to be a nonconductive fluid.

Finally, nothing in the file wrapper changes what was later disclosed in the Roos '667 patent, namely, that the device did not work because the device relied on secretions from bodily fluids to make the liquid conductive and that these secretions were insufficient to make the liquid electrically conductive. Patentee agrees with the Examiner's conclusions regarding the information in the '667 Roos patent which confirm that the '198 Roos patent does not disclose any medium that can be considered an electrically conductive fluid.

SUMMARY

Patentee believes all outstanding issue raised in the previous Office Action are addressed herein and that the claims are in condition for allowance.

The attorneys for the Patentee wish to express their gratitude to the Examiners for their courtesy in providing information regarding the status reexamination.

If the Examiner believes an interview will expedite allowance of this reexamination, please telephone the undersigned at (408) 736-0224.

Respectfully submitted,

Sanjay S. Bagade
Reg. No. 42,280

ArthroCare Corporation
680 Vaqueros Ave.
Sunnyvale, CA 94085-323
(408) 736-0224

I hereby certify that this correspondence is being deposited with the United States Postal Service Express Mail Post Office to Addressee service under 37 CFR 1.10 on the date indicated below, Express Mail No. EU627186305 and is addressed to Assistant Commissioner for Patents, Washington, D.C. 20231

On December 19, 2002

By Katie Zarzana

PATENT
Attorney Docket No.: **RE-EXAM – 1**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: EGGERS et al.

Reexamination of U.S. Patent No.: 5,697,536
Reexamination No.: 90/005,601
Reexamination Filed: December 30, 1999

Patent Filed: November 18, 1996
Patent Issued: December 16, 1997

For: **SYSTEM AND METHOD FOR ELECTROSURGICAL CUTTING AND ABLATION**

Examiner: Manuel Mendez

Art Unit: 3763

WRITTEN STATEMENT PER 37 C.F.R. §1.560(b)

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

This statement is made pursuant to 37 C.F.R. §1.560(b). As per M.P.E.P. §2281, this Statement is timely filed.

Statement Regarding Communications between the Office and John Raffle

John Raffle, attorney for Patentee, discussed U.S. Patent No. 4,116,198 to Roos ("Roos") with Examiner Mendez. Examiner Mendez expressed his opinion that the Roos patent is not prior art and that he would set forth his opinion in writing. Mr. Raffle expressed Patentee's position that the Roos patent is not prior art. In addition, Mr. Raffle expressed the Patentee's view that the Roos patent does not disclose electrically conducting fluid. Mr. Raffle also discussed the existence of a later filed patent

application to Roos (that issued as the '667 patent) which pointed out that the device disclosed in the Roos patent did not work because it did not use an electrically conducting fluid. Mr. Raffle also understood that the Roos patent was known to Examiner Mendez through his examination of commonly assigned patent applications.

Mr. Raffle also discussed a memorandum decision filed by Judge Orrick on December 2, 1998 in a lawsuit in the United States District Court for the Northern District of California between ArthroCare Corp. (as plaintiff) and Ethicon, Inc., Mitek Surgical Products, Inc., and Gynecare, Inc., (collectively as defendants) ("*Ethicon* litigation"). Mr. Raffle generally explained that Patentee sought a preliminary injunction in the *Ethicon* litigation; what a preliminary injunction is; what the decision was; what the decision meant in terms of the case; and that Judge Orrick denied Patentee's motion for a preliminary injunction. Mr. Raffle also provided a copy of the memorandum decision to Examiner Mendez. Mr. Raffle also told Examiner Mendez that Judge Orrick made a preliminary finding based on Roos and explained the importance of the Roos patent in the *Ethicon* litigation. On or about January 31, 2001, Examiner Kashnikow telephoned Mr. Raffle and asked that he provide him with the order granting the request for reexamination of the '536 patent.

Statement Regarding Communications between the Office and Sanjay Bagade

In May 2002, Examiner Mendez contacted Sanjay Bagade, attorney for Patentee, regarding claim 1. Examiner Mendez indicated that the Office found the claims allowable over the Roos patent, but questioned whether the phrase "an electrosurgical system for use with a high frequency power supply and an electrically conducting fluid supply" should be moved from the preamble of claim 1 to the body of the claim. Mr. Bagade stated his opinion that such an amendment was not appropriate. At Examiner Mendez's suggestion, Examiner Mendez, Mr. Bagade, and Examiner Brian Casler conducted a telephone interview to discuss whether the claim required such an amendment. During the interview, Examiner Mendez, Examiner Casler, and Mr. Bagade primarily discussed various court decisions (as cited by Examiner Mendez in the Office Action.) At the conclusion of the interview, the parties agreed that an amendment to the

claim was not necessary for the limitation to be considered in the assessment of patentability of the claims.

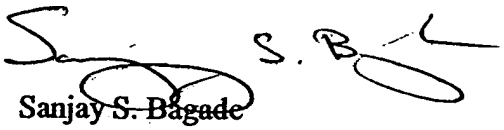
Statement Regarding Various Communications between the Office and John Raffle/Sanjay Bagade Regarding Status of the Reexamination

Both Mr. Raffle and Mr. Bagade have contacted either Examiner Mendez, Examiner Casler, or Examiner Kashnikow regarding various matters, including the status of the reexamination proceedings, various procedural matters regarding reexamination proceedings, and an estimation of when the Office would provide a first office action.

The reexamination proceeding was filed on December 30, 1999. As a result, the attorneys for the Patentee have made requests for the Office to issue an office action so that a timely response could be filed on the behalf of the Patentee. During these communications, either Mr. Raffle or Mr. Bagade have discussed various administrative issues such as the filing of information disclosure statements or the procedures for review of an office action in reexamination proceedings.

The attorneys for the Patentee wish to express their gratitude to the Examiners for their cooperation in providing information regarding the reexamination proceedings. The attorneys for Patentee respectfully request expedited review of this statement and accompanying response.

Respectfully submitted,



Sanjay S. Bagade
Reg. No. 42,280

ArthroCare Corporation
680 Vaqueros Ave.
Sunnyvale, CA 94085-3523
(408) 736-0224

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On December 19, 2002

By Katie Zarzana

PATENT
Attorney Docket No.: RE-EXAM – 1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: EGGERS et al.

Reexamination of U.S. Patent No.: 5,697,536
Reexamination No.: 90/005,601
Reexamination Filed: December 30, 1999

Patent Filed: November 18, 1996
Patent Issued: December 16, 1997

For: **SYSTEM AND METHOD FOR ELECTROSURGICAL CUTTING AND ABLATION**

Examiner: Manuel Mendez

Art Unit: 3763

AFFIDAVIT UNDER 37 C.F.R. 1.132

I, Michael A. Baker, being duly sworn, depose and say that I am President, Chief Executive Officer, and a director of ArthroCare Corporation (ArthroCare) and have held these positions since July 1997.

ArthroCare designs, develops, manufactures, and markets electrosurgical medical equipment for removing soft tissue from the body. Specifically, ArthroCare developed and continues to develop a broad technology platform for ablation of soft tissue. United States Patent No. 5,697,536 ("536 patent") is wholly owned by ArthroCare, and is the patent at issue in this reexamination proceeding. The '536 patent issued on December 16, 1997. I understand that shortly thereafter ArthroCare began marking certain of its products with the '536 patent number, including products discussed in this affidavit.

LONG FELT NEED

The '536 patent fulfills a long-felt need of surgeons who perform arthroscopic surgery. A common arthroscopic procedure is subacromial decompression, which is performed to correct chronic impingement in the shoulder.[1] Typically, subacromial decompression procedures had been performed with the "alternate use of a full radius shaver and an electrocautery device."[2] It has been reported that use of ArthroCare's products results in a reduction of procedure time by about 30%, which results in considerable cost savings.[3] In addition, it has been reported that use of ArthroCare's products reduces the risk of thermal injury to surrounding tissue, eliminates the need for glycine (which carries a small risk of toxicity), reduces the risk of electrical burns, has a high level of ablative precision and control, and creates smoother, more anatomical surfaces.[4] As a result, ArthroCare's products are now "an instrument of choice in arthroscopic shoulder procedures."[5]

INDUSTRY ACQUIESCENCE

ArthroCare has granted several royalty-bearing licenses to large, sophisticated medical device companies under the '536 patent. As early as 1995, Ethicon, Inc. ("Ethicon"), a Johnson & Johnson company, and Mitek Surgical Products ("Mitek"), a division of Ethicon, demonstrated an interest in ArthroCare's technology.[6] In early 1997, Ethicon, through Mitek, agreed to market and sell electrosurgical systems supplied by a United Kingdom company, Gyrus Medical, Ltd., that infringed the '536 patent. ArthroCare filed a lawsuit against Ethicon, Mitek, and Gynecare (a division of Ethicon) in the United States District Court for the Northern District of California in 1998. In 1999, in connection with the settlement of that lawsuit, ArthroCare granted Ethicon a license under, among others, U.S. Patent No. 5,697,536. Under the terms of that license agreement, Ethicon agreed to make a cash payment to ArthroCare in settlement of all past damages and royalties prior to the signing of the license agreement. In addition, Ethicon agreed to pay ArthroCare running royalties on net sales of licensed products.

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[1] See attached Ex. 1 (Stetson, "Time and Cost Savings of Coblation Technology in Subacromial Decompression, Research Outcomes in ArthroScopic Surgery (ArthroCare Corp., January 1999)).
[2] Id.
[3] Id.
[4] Id.
[5] Id.
[6] See attached Ex. 2.

Since that time, other companies have agreed to pay royalties for a license to use the '536 patented technology. For example, in 1998, ArthroCare granted Boston Scientific Corporation ("Boston Scientific") a license under, among others, the '536 patent. Under the terms of that license agreement, Boston Scientific agreed to pay ArthroCare an up-front license fee. Boston Scientific also agreed to pay ArthroCare a running royalty on certain net sales. Moreover, Boston Scientific agreed to pay ArthroCare an annual minimum royalty commencing on the first anniversary of receipt of FDA approval of the first licensed product, as that term is defined in the license agreement, and annually thereafter.

In 2000, Stryker Corporation ("Stryker") took a license under, among others, the '536 patent. Under the terms of that license, Stryker agreed to pay ArthroCare a non-refundable license fee. In addition, Stryker agreed to pay ArthroCare running royalties on net sales worldwide of certain licensed products.

In addition, Xomed Corporation, Collagen Aesthetics, Inc., Inamed Corporation, and ACMI Circon have sought and received royalty-bearing licenses from ArthroCare under, among others, the '536 patent.

As a result of all of these licensing activities, ArthroCare receives significant royalty revenue. ArthroCare received royalty revenues of $4.85 million in 1999, $3.62 million in 2000, $8.08 million in 2001, and $3.05 million for the 9 months ending September 30, 2002. ArthroCare notes that the royalty revenues are lower for 2002 due to the recognition of $1.7 million in fees due to the cancellation of agreements with former distributor partners in the third quarter of 2001.[7]

In 2001, Hugh Sharkey, who at that time was an Executive Vice President at Oratec Interventions Inc. ("Oratec"), contacted ArthroCare to express Oratec's interest in licensing ArthroCare's patents, including the '536 patent.[8] ArthroCare did not grant a license to Oratec. Thereafter, in March 2002, Smith & Nephew acquired Oratec and launched a bipolar ablation probe called the Saphyre that ArthroCare contends infringes the '536 patent. ArthroCare has added allegations of infringement related to the Saphyre to its infringement suit against Smith & Nephew in the U.S. District Court, District of Delaware, *ArthroCare v. Smith & Nephew*, 01-0504 SLR ("Smith & Nephew litigation"). Oratec's interest in acquiring a license to the '536 patent is

[7] See attached Ex. 3.
[8] See attached Ex. 4.

an additional indicia that the industry recognizes the strength of ArthroCare's patents, including the '536 patent.

COMMERCIAL SUCCESS

As noted above, ArthroCare's products were first sold in late 1995. At the end of fiscal year 2001, ArthroCare enjoyed approximately a 53% share of the United States market for RF powered arthroscopic devices. In addition, its licensees under the '536 patent, Stryker and Ethicon, enjoyed a combined share of the United States market for RF powered arthroscopic devices of approximately 21%. Thus, ArthroCare and its licensees under the '536 patent enjoy an approximately 74% share of the United States market for RF powered arthroscopic devices. Among other evidence of commercial success, this market share data demonstrates the commercial success enjoyed by ArthroCare's products and products covered by licenses ArthroCare granted under the '536 patent.

COPYING

ArthroCare is aware of evidence of copying by Smith & Nephew of ArthroCare's products, a portion of which is set forth here. In 1998, representatives of Smith & Nephew visited ArthroCare for the ostensible purpose of exploring a business relationship.[9] Smith & Nephew obtained numerous samples of ArthroCare's products.[10] Thereafter, Smith & Nephew began development of its own RF probe, known as the Control RF. Attached to this affidavit are certain documents produced by Smith & Nephew in response to ArthroCare's document requests in the Smith & Nephew litigation. As is clear from these documents, Smith & Nephew not only took measurements of the dimensions of ArthroCare's probes, but also conducted an "autopsy" of ArthroCare's probes to "learn about construction techniques, materials, switching, [and] electrical terminations."[11] ArthroCare believes that Smith & Nephew's efforts were directed at copying ArthroCare's products.

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[9] See attached Ex. 5.
[10] See attached Ex. 6.
[11] See attached Ex. 7 (SN21884-85 and SN21888-90).

SUMMARY

In my opinion, the factors listed above should be considered as objective indicia that the claims of the '536 patent are not obvious.

12/18/02

Michael A. Baker, President & CEO, ArthroCare Corporation — Date

State of California
ss.
County of Santa Clara

On December 18, 2002 before me, Kathleen Zarzana, Notary Public, personally appeared Michael A. Baker,

☒ personally known to me
☐ proved to me on the basis of satisfactory evidence

KATHLEEN ZARZANA
Commission # 1339634
Notary Public - California
Santa Clara County
My Comm. Expires Jan 13, 2006

to be the person(s) whose name(s) is/~~are~~ subscribed to the within instrument and acknowledged to me that ~~he/she/they~~ executed the same in ~~his/her/their~~ authorized capacity(~~ies~~), and that by ~~his/her/their~~ signature(~~s~~) on the instrument the person(~~s~~), or the entity upon behalf of which the person(~~s~~) acted, executed the instrument.

WITNESS my hand and official seal.

EXHIBIT 1

RESEARCH OUTCOMES IN
ARTHROSCOPIC SURGERY

VOLUME 3, NUMBER 2
JANUARY 1999

TIME AND COST SAVINGS OF COBLATION TECHNOLOGY IN SUBACROMIAL DECOMPRESSION

ArthroCare

Time and Cost Savings of Coblation® Technology in Subacromial Decompression

William B. Stetson, M.D.*

Arthroscopic subacromial decompression is a well accepted and successful technique for the treatment of chronic impingement syndrome of the shoulder.[1,2,3] Resection of the corocoacromial ligament and debridement of all soft tissues on the undersurface of the acromion and bursa is the first step of this procedure. This is typically accomplished with the alternate use of a full radius shaver and an electrocautery device, which is often an inefficient and time consuming component of the procedure.[4] However, there are now multifunctional surgical devices that combine tissue removal and hemostasis in a single instrument. Coblation® devices (ArthroCare Corp., Sunnyvale, CA) have been used in more than 250,000 subacromial decompressions since its commercial introduction four years ago. The Coblation system operates through a novel mechanism that produces tissue ablation with the ability to coagulate small and large vessels. The more efficient tissue removal achieved with this instrument should result in a significant reduction in procedure time and associated cost savings. The current study was undertaken to test this hypothesis.

Methods

The study prospectively randomized 50 consecutive patients undergoing arthroscopic subacromial decompression at the Missouri Bone and Joint Center. All patients had chronic impingement syndromes and had failed three months of conservative therapy. Standard diagnostic shoulder arthroscopy, bursoscopy and subacromial decompression were performed by the same surgeon. Thirty patients were treated using the Coblation device and a standard lactated ringer's solution. Twenty patients underwent surgery using the standard shaver and bovie approach. In these patients it was necessary to change to solutions of 5.0 percent glycine when electrocautery was used.

The time to perform subacromial decompression was selected as the endpoint of the study because it was possible to identify well defined start and completion points for this component of the procedure.

Results

Average procedure time in the Coblation group was 24:05 minutes (range 18:27 - 33:08) compared with 34:16 minutes when conventional technology was employed (range 25:03 – 48:25; p=0.05). No complications were noted in either group.

Discussion

Coblation technology employs novel bipolar surgical wands powered by enhanced radiofrequency energy. The Coblation method replaces the cellular pyrolysis and thermal cutting of standard monopolar electrosurgery with a cooler ablative process that produces cellular disintegration. Using an electrically conductive fluid (e.g., isotonic saline) in the gap between the wand and the tissue, Coblation devices create a highly charged particle layer that bombards tissue with high energy photons capable of breaking organic molecular bonds. This is achieved at temperatures of 40-70 degrees Celsius, dramatically cooler than the 400-600 degrees Celsius at which electrocautery devices operate. The features of Coblation include ablation, capable of removing tissue layers as fine as approximately 100 microns on average, and little or no thermal damage to surrounding tissue. Coblation devices also simultaneously coagulate small vessels and can be operated in coagulation mode if more aggressive hemostasis is required.

In this study, use of a Coblation device for subacromial decompression was associated with an average time savings of 12 minutes compared with standard instruments. This can be attributed to both the ablative efficiency and simultaneous coagulation of the Coblation device as well as to the avoidance of repeated instrument removal and reinsertion. If viewed in relation to surgical costs, because most surgical practice groups are charged by their institution for operating room time, a reduction in procedure time will be accompanied by a reduction in operating costs. Average total operating room costs at our institution, which include surgical suite, personnel and equipment charges, is approximately $500 per 15 minutes of

*Staff Physician, Arthritis, Orthopedic and Sports Medicine Center, Glendale, CA

Clinical Assistant Professor, Department of Orthopedics, USC Medical Center Los Angeles, CA

operating time. This figure is consistent with arthroscopic operating costs reported by other authors.[5,6] Based on this cost, a 10-minute reduction in procedure time will be associated with a savings of $333. Allowing for the cost of a Coblation wand (approximately $125) and that of a standard subacromial bovie (approximately $50), this results in an overall savings of approximately $260 per case.

In this study, we restricted evaluation of time to the component of the surgery dealing with subacromial decompression. However, in most shoulder arthroscopies performed for impingement syndromes it is generally necessary also to perform a Mumford or mini-Mumford procedure. Because of the highly vascularized nature of this tissue, bleeding is a frequent problem. The Coblation wand is well suited for this purpose because of its ability to establish hemostasis in both small and large vessels. If use of the wand is extended to this component of the procedure, we project that an additional time savings of 7 to 8 minutes could be realized. This would result in a total savings of as much as 20 minutes per procedure. This represents a potential one-third reduction in total procedure time with the use of a Coblation device assuming that the equivalent procedure using standard arthroscopic techniques would require 60 minutes, a figure consistent with experience at our institution.

The benefits of Coblation are not limited to those of time and cost. The technology enables controlled ablation that results in smoother, more anatomical surfaces than those produced with a bovie or mechanical shaver, while reducing the risk of thermal injury to surrounding tissue. In vivo findings demonstrate that cells immediately adjacent to the zone of ablation remain viable following Coblation. Eliminating the need for glycine is also advantageous. Although small, the risk of blindness or tissue toxicity with this compound is real and its use should be avoided whenever possible. Finally, the bipolar aspect of the Coblation system eliminates the risk of electrical burns, one of the most frequent nonjoint complications of standard arthroscopy.

	Coblation	Bovie/Shaver
Average Procedure Time (range)	24:05 min (18:27-33:08)	34:16 min* (25:03-48:25)
Operating Room Costs**	$800	$1,140
Instrument Costs	$125	$50
Net Cost Savings with Coblation	$265	-

* $p = 0.05$

** Based on a projected cost of $500 per 15 minutes of operating time.

Table 1. Time and Cost Savings with Coblation vs. Bovie/Shaver Technique

Conclusion

Use of Coblation devices for soft tissue resection and debridement in arthroscopic subacromial decompression reduced procedure time by 30 percent compared with the use of a shaver and electrocautery bovie. This can result in a savings of as much as $260 per procedure based on common operating room fees and instrument costs. Coblation technology is also associated with a high level of ablative precision and control, creation of anatomical surfaces, and prevention of thermal injury to surrounding tissue. Secondarily, Coblation devices eliminate the risk of glycine toxicity and electrical burns that accompany the use of standard electrosurgical instruments. This combination of clinical and economic factors makes Coblation technology an instrument of choice in arthroscopic shoulder surgery.

Research Outcomes in Arthroscopic Surgery is a continuing series published by ArthroCare Corporation. Each issue will explore research findings and emerging treatments in arthroscopic surgery.

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6. Trieshmann, HW. Knee arthroscopy: A cost analysis of general and local anesthesia. Arthroscopy 1996; 12:60-3.

FOR MORE INFORMATION:

ArthroCare Corporation
680 Vaqueros Avenue
Sunnyvale, CA 94085

800-797-6520 (U.S. only)
408-736-0224
408-736-0226 (fax)

Additional information about ArthroCare Corporation products is available upon request.

P/N 04925, Rev B

ArthroCare

EXHIBIT 2

ETHICON, INC.
a Johnson & Johnson company
P.O. BOX 151
SOMERVILLE - NEW JERSEY - 08876-0151

September 29, 1995

Hira V. Thapliyal, Ph.D.
Arthrocare
595 No. Pastoria Avenue
Sunnyvale, CA 94086

Dear Hira,

Thank you so much for arranging our meeting on Wednesday morning. Dave and I were very pleased with the openness with which you conducted the meeting and hope you found the meeting useful from Arthrocare's perspective. We remain interested in talking with you further about this opportunity, and are eager to see it used in surgery. I will be back in touch as soon as I return to the U.S. next week.

Sincerely,

Pat

Patrick J. O'Neill, Ph.D.
Vice President
Growth Technologies &
New Business Development

cc: D. Lehman

ETHICON, INC.
a Johnson & Johnson company
P.O. BOX 151
SOMERVILLE - NEW JERSEY - 08876-0151

March 18, 1996

Hira V. Thapliyal, PhD
President & CEO
Arthrocare Corporation
595 N. Pastoria Avenue
Sunnyvale, CA 94086

Dear Hira,

I want to thank you, Larry and Phil for visiting Somerville last Friday. We found the discussions which took place very constructive. It certainly was helpful for us to better understand your perspective on the various applications for your multi-electrode bipolar technology and hear what plans you were able to share. I hope you took away not only our continued interest in the technology but also the position in which we find ourselves following your public stock offering.

From our conversations, I believe we share an interest in continuing to explore relationships between us which will meet our respective business objectives. As a take away from our meeting, we agreed to discuss options internally and get back to the other party with suggestions on potential ways to proceed.

In the meantime, we will continue to refine our analysis of not only the Sports Medicine opportunity (both U.S. & International), but also for other identified applications which may fit with either Ethicon or other J&J operating companies.

It would help our assessment process if we could purchase one or two Arthrowand systems. These would be used within our own facilities for the purpose of carrying out independent evaluations with surgeons of the various specialties. It would also be helpful if we can continue to contact a few of your key users or Scientific Advisory Board members regarding their thoughts on the technology. These discussions will be limited to the Sports Medicine application and will be coordinated with you.

I look forward to talking with you soon.

Sincerely,

Pat

P. J. O'Neill, Ph.D.
Vice President
Growth Technologies &
New Business Development

EXHIBIT 3

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-Q

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended September 28, 2002.

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from to

Commission File Number: 0-27422

ArthroCare Corporation
(Exact name of registrant as specified in its charter)

Delaware	**94-3180312**
(State of incorporation)	**(I.R.S. Employer Identification No.)**

680 Vaqueros Avenue
Sunnyvale, California 94085
(Address of principal executive offices)

(408) 736-0224
(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐.

The number of shares outstanding of the registrant's common stock as of November 1, 2002 was 20,963,930.

ARTHROCARE CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF INCOME
(In th usands, except per share data)
(Unaudited)

	Three Months Ended		Nine Months Ended	
	September 30, 2002	September 30, 2001	September 30, 2002	September 30, 2001
evenues:				
Product sales	$ 21,332	$ 17,975	$ 61,329	$ 53,505
Royalties, fees and other	879	2,287	3,054	7,075
Total revenues	22,211	20,262	64,383	60,580
ost of product sales	7,981	7,522	22,758	21,390
Gross profit	14,230	12,740	41,625	39,190
perating expenses:				
Research and development	2,188	1,973	6,472	5,869
Sales and marketing	9,011	8,253	26,270	22,471
General and administrative	2,458	1,426	6,861	3,756
Total operating expenses	13,657	11,652	39,603	32,096
Income from operations	573	1,088	2,022	7,094
Interest and other income, net	377	2,961	1,231	5,103
Income before income tax provision	950	4,049	3,253	12,197
Income tax provision	304	1,458	1,064	4,402
Net income	$ 646	$ 2,591	$ 2,189	$ 7,795
Basic net income per share	$ 0.03	$ 0.12	$ 0.10	$ 0.35
Shares used in computing basic net income per share	21,085	22,477	21,595	22,428
Diluted net income per share	$ 0.03	$ 0.11	$ 0.10	$ 0.33
Shares used in computing diluted net income per share	22,060	23,860	22,514	23,503

The accompanying notes are an integral part of these condensed consolidated financial statements

our arthroscopy disposable device revenue is being generated by the sale of disposables for use in knee procedures.

Royalties, fees and other were $0.9 million for the third quarter of 2002, as compared to $2.3 million for the third quarter of 2001. The decrease was primarily due to the recognition of $1.7 million in fees due to the cancellation of agreements with former distributor partners in the third quarter of 2001.

Cost of Product Sales

Cost of product sales was $8.0 million for the three-month period ended September 30, 2002 or 37% of product revenues, as compared with $7.5 million or 42% of product revenues in the third quarter of 2001. The decrease in cost as a percentage of product sales for the third quarter of 2002 as compared to the prior year period is attributable to the increased efficiency of the manufacturing operations. As planned, Arthrocare's new Costa Rica facility continued shipping sub-assemblies to the Sunnyvale facility in the third quarter and is expected to contribute to gross margin improvements in the fourth quarter of 2002 and fiscal 2003.

Operating Expenses

Research and development expenses were $2.2 million or 10% of product sales, for the three-month period ended September 30, 2002, as compared to $2.0 million or 11% of product sales for the same period in 2001. The increase in spending in the third quarter of 2002 is primarily due to continuing development of new products in our currently commercialized markets, continuing our development efforts for potential additional products and continuing to maintain and develop our patent position.

We expect to increase the dollar amount of research and development spending through continued expenditures on new product development, regulatory affairs, clinical studies and patents.

Sales and marketing expenses were $9.0 million or 42% of product sales, for the three-month period ended September 30, 2002, as compared to $8.3 million or 46% of product sales during the same period in 2001. The increase in spending in the third quarter of 2002 was primarily due to $0.7 million associated with the accrual of higher commissions resulting from increased sales, $0.4 million due to the hiring of new direct sales representatives, partially offset by $0.3 million lower expenses related to marketing research and promotional activities.

We anticipate that sales and marketing spending may continue to increase slightly in absolute dollars due to the expansion of our distribution and sales force capabilities to address the ENT and spinal surgery markets, higher commissions from increased sales, the additional cost of penetrating international markets, higher promotional, demonstration and sample expenses and, additional investments in the sales, marketing

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

ANNUAL REPORT
PURSUANT TO SECTION 13 OR 15(d)
OF THE SECUTITIES EXCHANGE ACT OF 1934

For the fiscal year ended	Commission File Number
December 29, 2001	0-27422

ARTHROCARE CORPORATION
(Exact name of Registrant as specified in its charter)

Delaware	94-3180312
(State or other jurisdiction of Incorporation or organization)	(I.R.S. employer Identification number)

680 Vaqueros Avenue, Sunnyvale, California 94085
(Address of principal executive offices and zip code)

(408) 936-0224
(Registrant's telephone number, including area code)

Securities registered pursuant	
To 12 (b) of the Act:	None
Securities registered pursuant	Common Stock, $0.001 Par Value;
To section 12 (g) of the Act:	Preferred Purchase Rights

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15 (d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes [x] No [ ]

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. [ ]

As of March 15, 2002, the aggregate market value of the voting stock held by non-affiliates of the Registrant was $175,781,675 (based upon the closing sales price of such stock as reported by The Nasdaq Stock Market on such date). Shares of Common Stock held by each officer, director, and holder of 5% or more of the outstanding Common Stock on that date have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 15, 2002, the number of outstanding shares of the Registrant's Common Stock was 21,836,267.

DOCUMENTS INCORPORATED BY REFERENCE

Certain information required by items 10, 11, 12, and 13 of Part III of Form 10-K is incorporated by reference from the Registrant's proxy statement for the 2002 Annual Stockholders Meeting (the Proxy Statement) which will be filed with the Securities and Exchange Commission within 120 days after the close of the Registrant's fiscal year ended December 29, 2001.

	Year Ended December 31, (in thousands, except per share data)				
	2001	2000	1999	1998	1997
Statements of Operations Data:					
Product sales	$ 75,247	$ 64,012	$ 44,219	$ 24,624	$ 12,796
Royalties, fees and other	8,075	3,615	4,857	3,292	–
Total Revenues	83,322	67,627	49,076	27,916	12,796
Gross profit	55,631	41,965	29,891	15,548	4,301
Operating expenses	47,941	34,467	25,242	18,625	13,401
Net income (loss) before cumulative Effect of change in accounting Principle	10,060	15,845	5,543	(2,141)	(7,688)
Cumulative effect on prior years of The application of SAB 101	–	(4,300)	–	–	–
Net income (loss)	10,060	11,545	5,543	(2,141)	(7,688)
Basic net income (loss) per share	$ .45	$ .53	$ .29	$ (0.12)	$ (0.44)
Diluted net income (loss) per share	$ .43	$ .50	$ .27	$ (0.12)	$ (0.44)

	December 31				
	2001	2000	1999	1998	1997
Balance Sheet Data:					
Cash, cash equivalents And available-for-sale securities (including long-term portion)	$ 76,695	$ 86,814	$ 79,607	$ 8,058	$ 19,872
Working capital	98,642	97,013	85,118	16,973	20,342
Total assets	133,697	140,462	110,039	27,760	26,675
Total stockholders' equity (1)	125,093	126,345	102,883	22,305	23,546

(1) We have not declared any cash dividends on our common stock since our inception and we do not anticipate paying cash dividends in the foreseeable future.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion should be read in conjunction with the consolidated financial statements and notes thereto appearing elsewhere in this Form 10-K. Statement in this Management's Discussion and Analysis of Financial Condition and Results of Operations and elsewhere in this annual report on Form 10-K which express that we "believe," "anticipate," "expect" or "plan to" as well as other statements which are not historical fact, are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Actual events or results may differ materially as a result of the risks and uncertainties described herein and elsewhere including, but not limited to, those factors discussed in "ADDITIONAL FACTORS THAT MAY AFFECT FUTURE RESULTS" set forth in Part I of this Report as well as other risks and uncertainties in the documents incorporated herein by reference.

Overview

We are a medical device company that develops, manufactures and markets products based on our patented Coblation technology. Our products allow surgeons to operate with increased precision and accuracy, limiting damage to surrounding tissue thereby reduction pain and speeding recovery for the patient. Our products operate at lower temperatures than traditional electrosurgical or laser surgery tools and enable surgeons to ablate, shrink, sculpt, cut, or aspirate soft-tissue surgery procedures with one multi-purpose surgical system.

EXHIBIT 4

ORATEC®

September 2, 2001

John Raffle Esq.
Arthrocare Corporation
595 North Pastoria Ave
Sunnyvale, CA 94086-2916

Dear Mr. Raffle,

I am following up on a conversation that Mike Baker and Ken Anstey had last week about working out a licensing arrangement between Oratec and Arthrocare. It was apparently left that we (Oratec) would provide you with some suggested language for the agreement, for your review and comment.

I have taken the approach of describing a "field of use" as opposed to specific patent claims in an attempt to make administration of such an agreement as straight forward as possible. My suggestion is as follows:

> *Field of Use* *RF bipolar probes with an active, and a return electrode on the shaft, for the removal of soft tissue; to include probes with suction and irrigation capabilities; but excluding:*
>
> *(1) inductor augmented circuits/reactive component designs, and*
> *(2) individually wired, multi-poled electrode configurations*
> *(3) (whatever other specifics may be necessary* vis a vis *your other agreements)* . .

Of course the entire agreement will need to cover many other provisions, standard to this type of arrangement, but I think the IP portion is probably the first aspect that needs to be defined. Let me know what you think.

Sincerely,

Hugh Sharkey
Executive Vice President

cc.: Ken Anstey

ORATEC
Interventions, Inc.

3700 Haven Court
Menlo Park, CA
94025

Phone:
(650) 369-9904

EXHIBIT 5

Endoscopy Division
Smith & Nephew, Inc.
160 Dascomb Road, Andover, MA 01810 U.S.A.
Telephone: 978-749-1000
Telefax: 978-749-1599

Smith+Nephew

Confidential Communication

July 17, 1998

Ms. Christine Hanni
Chief Financial Officer
ArthroCare Corporation
595 North Pastoria Avenue
Sunnyvale, CA 94086

Dear Christine:

I enjoyed speaking with you earlier this week to begin exploration of future business opportunities between ArthroCare and Smith & Nephew. My associates and I are pleased to visit with you and ArthroCare's President and CEO, Michael Baker on Monday, August 10, 1998 to facilitate mutual discussion of our company capabilities and how we can work together to address common market objectives.

Doug Macarthur (Group Manager, R&D) , Todd Plevinsky (Senior Product Manager) and David Balford (Technology Business Manager) will arrive at 8:30 AM to engage in discussion with you and Michael Baker on matters related to the following proposed agenda.

AGENDA FOR MONDAY, AUGUST 10, 1998

David Balford (8:30-9:15)

- General introduction of participants.
- Explanation of Purpose.
- Slide presentation "Who is Smith & Nephew" ?
- The power of Smith & Nephew global sales.
- Successful strategic alliances.
- Successful acquisitions.

Doug Macarthur (9:15 - 10:00)

- Discussion of ArthroCare's technology and how it might "fill the hole" in the Smith & Nephew Endoscopy product line.
- Discussion of Smith & Nephew Endoscopy's R&D capabilities including areas of strength and focus. Discourse on how a synergistic relationship with ArthroCare R&D could be a desirable way to achieve the goal of filling the void.
- Discussion of ArthroCare's emerging technology to appreciate how joint development projects could be entertained to strengthen the market position of both companies.

Todd Plevinsky (10:00 - 10:45)

- Strategic partnership advantages
- Why Smith & Nephew Endoscopy is interested in collaborative exploration.
- Modes of opportunity.

ArthroCare Presentation

We welcome hearing ArthroCare's thoughts and responses to these bullet points presented in similar fashion. Smith & Nephew anticipates utilizing simple 35mm slide and overhead slide presentation medium to advance their ideas. The main purpose of our visit and presentation is to express a sincere desire in working with ArthroCare to address our common commercial objectives through mutual exchange of ideas.

I look forward to receiving your completed confidentiality agreement in the near future and hearing any thoughts which might improve the nature and character of our meeting together.

Sincerely,

David Balford
Technology Business Manager

cc: L. Curtis, W. Fox, J. Myhre

EXHIBIT 6

FAX

Date 9-22-98

TO: Michael Baker

Number of pages including cover sheet 2

FROM: Donna Ballch
Smith & Nephew Endoscopy
160 Dascomb Road
Andover, MA 01810

Phone 978-749-1081
Fax Phone 978-749-1098

Phone
Fax Phone 888-994-2782

CC: 530 9143

REMARKS: ☐ Urgent ☐ For your review ☐ Reply ASAP ☐ Please Comment

Please process the attached purchase order 840511.
Please advise on pricing and delivery if applicable.

Any questions please feel free to call.

Thank you

Smith & Nephew Endoscopy, Inc.
[illegible] Andover, MA 01810 U.S.A.
Telephone (508) 470-2000 Toll Free: 1-800-343-5186
Fax (508) 470-2227
Smith+Nephew

THIS AREA FOR
PURCHASING USE ONLY

PURCHASE ORDER NO. 840511

REQ NO. A 76230	ISSUE DATE	F.O.B.	SHIP VIA	CONFIRM TO Michael
SUPPLIER SHIP DATE	ARRIVAL DATE		COST CENTER 806	ACCOUNT NO. 6.0040.000

SUPPLIER: ARTHROCARE — SUPPLIER NO.
ADDRESS: 595 North Pastoria Ave
CITY: Sunnyvale STATE: CA ZIP: 94806-2916
ATTENTION: Michael Baker

NOTE ▶ ORIGINAL PURCHASE ORDER ☐ CONFIRMATION ☐
TAX EXEMPT ☐ TAXABLE ☐
BUYER: SR
TAX-EXEMPT NO. 600-040-127

PURCHASE REQUISITION

PART NUMBER OR ITEM NO.	QUANTITY	DESCRIPTION OF ITEM	UNIT PRICE	TOTAL PRICE
1	1	H 7079-00 SYSTEM 2000 (QUOTE ITEM 1)	7500 —	7500 —
2	10	A52530-01 COVAC 50 WAND (QUOTE ITEM 3)	452 —	1500 —
3	10	A1345-01 ELIMINATOR WAND (QUOTE ITEM 5)	125 —	1250 —
4	10	A1630-01 CAPS-X WAND	190 —	1900 —
5	10	A4330-01 SABER 30 WAND	120 —	1200 —
		TOTAL		$13,350

ARTC 20006
HIGHLY CONFIDENTIAL
ATTORNEYS' EYES ONLY

SUGGESTED SUPPLIER _____
ADDRESS _____
CONTACT _____ TEL. 800-797-2916
FAX NO. 888-994-2787

REQUESTED BY D. Mcarthur DEPT NO. 806
APPROVED BY _____
APPROVED BY _____ 9/22/98
APPROVED BY _____
APPROVED BY _____

ORIGINAL

EXHIBIT 7

RF Probe Competitive Analysis

	ArthroCare Cat No. AS 2530-01 CoVac 50; 3.0mm 50° Suction	**ArthroCare** Cat No. A1630-01 3.0mm 45° CAPS-X Low Temperature Treatment	**Mitek** Cat No. 225301 VAPR Side Effect Electrode, 3.5mm x 160mm	**ORATEC** Cat No. 901001 TAC-S ElectroThermal Probe
Outer Package	White paperboard box, non printed, 10.90" x 3.25" x .90"	White paperboard box, non printed, 10.90" x 3.25" x .90"	White paperboard box, non printed, 13.00" x 2.83" x 1.33"	White paperboard box, pre-printed, 14.50" x 4.30" x 1.03"
Labeling	Single Label, Product Ident.	Single Label, Product Ident.	Two Labels: 1. Product Ident w/ Intl Symbols 2: Multi Language and EU Rep.	Two Labels: 1. Product Ident 2. Seal Label
CE Mark	NO	NO	YES	NO
Product Package	Rigid PETE Blister, Blank Tyvek Lid with Printed Label	Rigid PETE Blister, Blank Tyvek Lid with Printed Label	Rigid Blister, pre-printed tyvek lid with label for multi language translations	Rigid Blister, non-printed tyvek lid inside a tyvek / poly pouch. Blank tyvek, label on poly side
Disposable Probe Dimensions	Probe: Ø.153 x 5.00L Handle: Ø.740 x 3.00L Grip w/ Cable Ø.740 x 5.5"L	Probe: Ø.153 x 5.00L Handle: Ø.740 x 3.00L Grip w/ Cable Ø.740 x 5.5"L	Probe: Ø.142 x 6.45L Handle: Ø.934 x 2.4 Grip w/ Cable: Ø1.00 x 6.5"L	Probe: Ø.135 x 5.90L Handle: Ø.65 x 4.31L Overall w/ Cable: Ø.65 x 5.75"L
Weight	TBD	TBD	TBD	TBD
Probe Material	TBD	TBD	TBD	TBD
Handle Material	TBD	TBD	TBD	TBD
Insulation	TBD	TBD	TBD	TBD
Suction	YES	NO	NO	No
Interconnect	Custom 27 pin header with gold plated pins, 19 used	Custom 27 pin header with gold plated pins, 9 used	Custom gold plated contact pads	Insert molded REDEL connector, 4 pin.
IFU	NO		Yes, 11 Languages	Yes, English Only
Cable	Custom, Peek Connectors and Silicone Cable / flex relief(s)	Custom, Peek Connectors and Silicone Cable / flex relief(s)	Custom 3 prong plug and handle, Reusable(?)	Reusable w/ Redel connectors, Silicon jacket and flex relief(s)

S&N0021884

REDACTED

	10.5 ft Long	10.5 ft Long	10 ft long	10 ft long
Sterilization: Method and Shelf Life	Unknown	Unknown	Gamma Radiation 5 Years	Sterrad 1 Year

Autopsy Criteria:

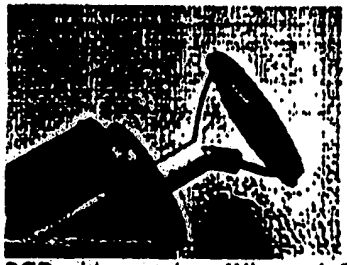
General: Examine each of the competitive products to learn about construction techniques, materials, switching, electrical terminations.

Mitek:

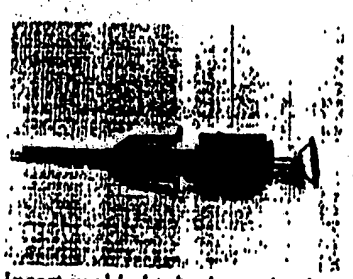
Probe threads and seals into a reusable handle / cord assembly. Electrical connection through 3 contact pads on the PCB.
Probe shown on top: Stainless steel tube; .100 I.D. Single conductor to active electrode. Return through tube.
Left to Right:

1. Retainer: Holds the PCB and covers the solder connections.
2. Tube Sub-assembly. Tube insert molded into plastic carrier with PCB attached.
3. PVC tube. Stabilizes probe shaft in front end.
4. Molded front end of probe handle.

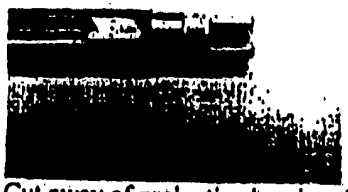
Active Electrode: Spring crimped around solid rod nested in insulator.



PCB with capacitor. Wire on left connects capacitor to the tube. Wire on right is the active conductor. Silicone tube insulates the conductor as it bends over the tube end.

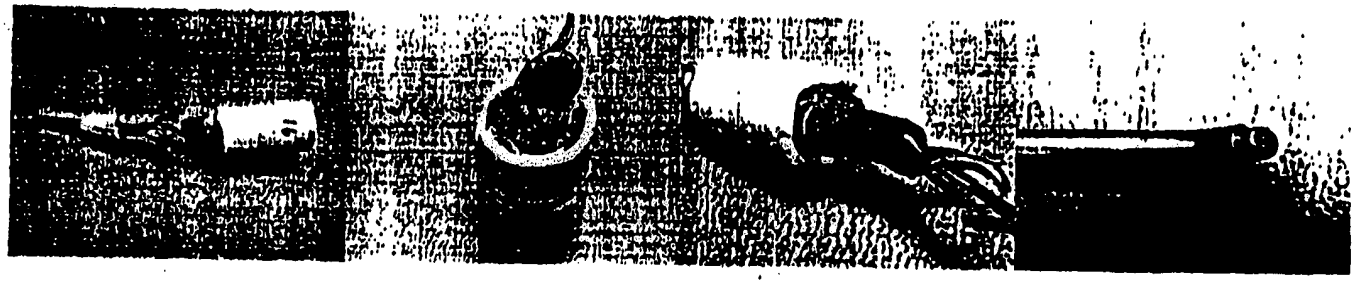


Insert molded tube into plastic carrier. Subassembly snaps into the front end of the probe handle.



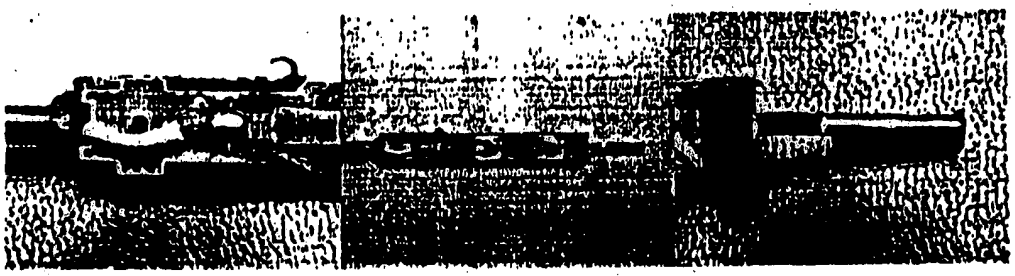
Cut away of probe tip showing the single conductor to the active electrode.

ArthroCare: p/n A130-01 (without suction)



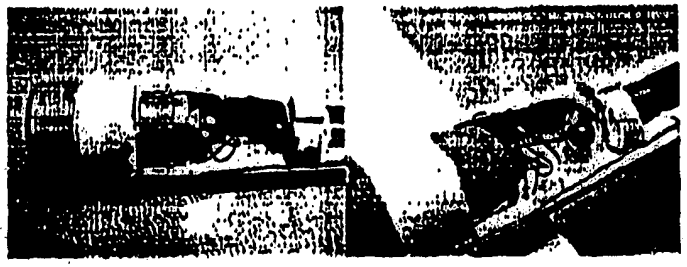
Incorporates a molded plastic handle having a snap-in header board. Radial Capacitor, 332K across 2 pins. PCB and tube end is conformal coated. One wire is a bare conductor in a clear tube connected to one side of the capacitor. Tube has many individual electrode wires running down it's full length to a complex array at the tip. Outer tube is insulated except for at the tip just aft of the bend.

Dyonics: Electro-surgical pen.



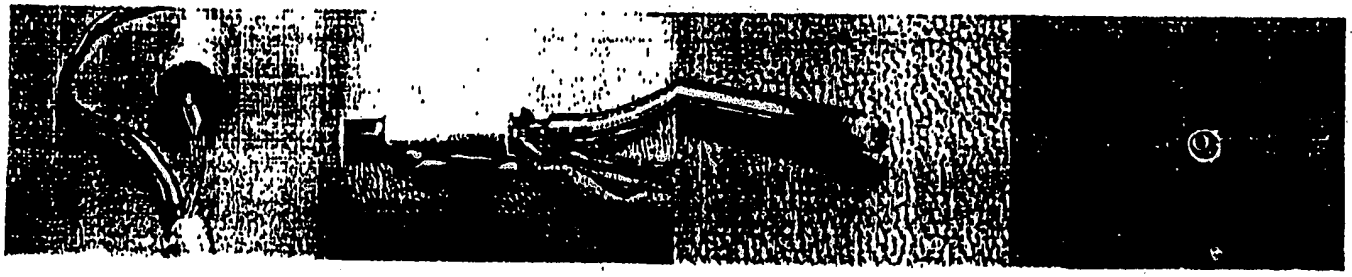
Switch assembly in molded handle. PCB and dome switches for Cut and Coag encapsulated in Kapton tape. Receptacle for probe connection. Three conductor cable.

Oratec:



Probe shaft with plastic hub and Redel receptacle insert molded into handle. Note thick wall section of tube and small gauge wires.

ArthroCare, p/n AS2530-01 with Suction



Incorporates a molded plastic handle having a snap-in header board. PCB and tube end is conformal coated. One wire is a bare conductor in a clear tube. Tube has many individual electrode wires running down it's full length to a complex array at the tip. Suction Tube runs down the length of the stainless steel tube. PVC tube is bonded to the suction tube inside the handle and exists the handle along the side and is sealed with Epoxy. Outer tube is insulated except for at the tip just aft of the bend.

I hereby certify that this correspondence is being deposited with the United States Postal Service Express Mail Post Office to Addressee service under 37 CFR 1.10 on the date indicated below, Express Mail Label No. EU627186305 and is addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231

On December 19, 2002

By Katie Zarzana

PATENT

Attorney Docket No.: 16238-000610

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of:

PHILIP E. EGGERS et al.

Application No. 90/005,601

Reexamination of Patent No.: 5,697,536

Issued: December 16, 1997

For: SYSTEM AND METHOD FOR ELECTROSURGICAL CUTTING AND ABLATION

Examiner: M. Mendez

Art Unit: 3739

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §1.97 and §1.98

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

The references cited on attached form PTO-1449 are being called to the attention of the Examiner. These references were brought to Applicant's attention through the *Smith & Nephew* litigation referred to in the previously submitted IDS. Also being submitted are the following documents:

i) Correspondence from Kurtis MacFerrin to Perry Clark dated September 10, 2002 with Exhibit A (2 pgs), Exhibit B (11 pgs), Exhibit E (3 pgs).

ii) Correspondence from Kurtis MacFerrin to Perry Clark dated October 9, 2002 with Exhibit A (2 pgs), Exhibit B (22 pgs), Exhibit E (7 pgs).

iii) File History of U.S. Patent No. 4,116,198 Roos.

If the Examiner believes a telephone conference would expedite prosecution of this re-examination, please call the undersigned at (408) 735-6323.

Respectfully submitted,

Sanjay S. Bagade
Reg. No. 42,280

ArthroCare Corporation
680 Vaqueros Ave.
Sunnyvale, CA 94085
(408) 736-0224

FORM PTO-1449 (Modified) LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)	Attorney Docket No. 16238-000610	Patent No.: *5,697,536*
	Applicant: PHILIP E. EGGERS et al.	
	Issue Date: *December 16, 1997*	Group:

Reference Designation	U.S. PATENT DOCUMENTS					
Examiner Initial	Document No.	Date	Name	Class	Sub-class	Filing Date
___ AA						
___ AB						
___ AC						
___ AD						
___ AE						
___ AF						
	FOREIGN PATENT DOCUMENTS					
						Translation (yes/no)
___ AG						
___ AH						
___ AI						

OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)	
___ AJ	Correspondence from C. Larson *Dept. of Health & Human Services* dated April 22, 1991 (3pgs)
___ AK	Summary of Safety and Effective Information (2pgs)
___ AL	Correspondence from R. Britain *Dept. of Health & Human Services* dated August 12, 1985
___ AM	Correspondence from J. Malis *Valley Forge* dated July 25, 1985 (3pgs)
___ AN	L. Malis *J. Neurosurg.* Vol. 85, pp. 970-975 (1996).
___ AO	Excerpt from seminar by L. Malis, MD *1995 American Assoc. of Neurologicla Surgeons Meeting* (1pg)
___ AP	L. Malis *The Value of Irrigation During Bipolar Coagulation* (1pg)
___ AQ	L. Malis *New Trends in Microsurgery and Applied Technology* (pgs 9-16)
___ AR	*Codman Bipolar Electrosurgery Products* brochure (8 pgs)
___ AS	*The MALIS Bipolar Coagulating and Bipolar Cutting System CMC-II* brochure (2pgs)
___ AT	"Valley Forge's new products" *Clinica* Vol. 475, p. 5 (1991)
___ AU	The MALIS Bipolar Electrosurgical Systems CMC-II (Catalog 80-1170) 14 pgs
EXAMINER	DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: ASSISTANT COMMISSIONER FOR PATENTS
Washington, D.C. 20231

APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
90/005,601	DECEMBER 30, 1999	5,697,536	16238-00610

ARTHROCARE CORPORATION
680 VAQUEROS AVENUE
SUNNYVALE CA 94085-3523

EXAMINER	
ART UNIT	**PAPER**
MENDEZ, M.	13

DATE MAILED: NOVEMBER 15, 2002 AK

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

cc: William C. Fuess, 3rd party attorney

PTO-90C (Rev.3-98)

Office Action in Ex Parte Reexamination	Control No. 90/005,601	Patent Under Reexamination	
	Examiner Manuel Mendez	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

a☒ Responsive to the communication(s) filed on *19 June 2002*. b☐ This action is made FINAL.

c☐ A statement under 37 CFR 1.530 has not been received from the patent owner.

A shortened statutory period for response to this action is set to expire ~~3~~ 2 (TWO) month(s) from the mailing date of this letter. Failure to respond within the period for response will result in termination of the proceeding and issuance of an *ex parte* reexamination certificate in accordance with this action. 37 CFR 1.550(d). **EXTENSIONS OF TIME ARE GOVERNED BY 37 CFR 1.550(c).** If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Information Disclosure Statement, PTO-1449.
3. ☐ Interview Summary, PTO-474.
4. ☒ *See Continuation Sheet*.

Part II SUMMARY OF ACTION

1a. ☒ Claims *1-64* are subject to reexamination.

1b. ☐ Claims _____ are not subject to reexamination.

2. ☐ Claims _____ have been canceled in the present reexamination proceeding.

3. ☐ Claims _____ are patentable and/or confirmed.

4. ☒ Claims *1-64* are rejected.

5. ☐ Claims _____ are objected to.

6. ☐ The drawings, filed on _____ are acceptable.

7. ☐ The proposed drawing correction, filed on _____ has been (7a)☐ approved (7b)☐ disapproved.

8. ☐ Acknowledgment is made of the priority claim under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some* c)☐ None of the certified copies have

1☐ been received.

2☐ not been received.

3☐ been filed in Application No. _____.

4☐ been filed in reexamination Control No. _____.

5☐ been received by the International Bureau in PCT application No. _____.

* See the attached detailed Office action for a list of the certified copies not received.

9. ☐ Since the proceeding appears to be in condition for issuance of an *ex parte* reexamination certificate except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte* Quayle, 1935 C.D. 11, 453 O.G. 213.

10. ☐ Other: _____

cc: Requester (if third party requester)

Continuation of Part I. 4. : IDS dated 10/16/01 and IDS dated 06/19/02/.

DETAILED ACTION

Introduction

The prosecution of Reexamination No. 90/005,601 originated with the filing of a Reexamination Request on December 30, 1999. The Request indicated that the requester considered claims 1-3, 14, 16, 22, 27, 30, 33, 38, 41-48, 55, 57, 60, and 63, of Eggers, et al., U.S. Patent Number 5,697,536, referenced hereafter as **Eggers '536**, as being anticipated by Roos, U.S. Patent Number 4,116,198, referenced hereafter as **Roos '198**. After a complete review of the merits of the Request, the examiner of record concluded that Roos '198 raised a substantial question of patentability. Consequently, an order granting the Request for Reexamination was mailed on February 2, 2000. The order was mailed for a second time on October 27, 2000.

The arguments presented by the Request concerning Roos '198 were addressed in a final decision by the examiner of record and reviewed by a board of primary examiners that convened to analyze the decision and make a final determination. However, before the mailing of the written decision, a new Information Disclosure Statement (IDS) was timely received on June 19, 2002. The IDS comprises of evidentiary documents pertinent to pending litigation at the United States District Court in the State of Delaware (Arthrocare Suit-Delaware, USDC-D. DEL.-C.A. No. 01-504-SLR).

In view of the new documents submitted by the IDS, the examiner of record has decided to divide this prosecution in two sections. The first section addresses the issues originally presented by the Request concerning Roos '198 and summarizes the patentability conclusion as it was decided by the examiner of record prior to the receipt of the new IDS. Finally, the second section addresses new relevant references as listed in the IDS received on June 19, 2002, and more specifically, the Supplemental Invalidity Response included in the submitted IDS package.

Section I: Analysis of the Roos Patent

After carefull consideration and review of Roos '198, it is hereby found that Roos '198 does not anticipate or render obvious any of the independent claims of record for a variety of reasons that will be discussed below.

Interpretation of the Preamble

The preamble of claim 1, discloses "an electrosurgical system for use with a high frequency power supply and an electrically conducting fluid supply". It is noted that whether a preamble constitutes a limitation to a claim is a matter to be determined by the facts of each case in view of the claimed invention as a whole. See, In re Stencel, 828 F.2d 751, 4 USPQ2d 1071, 1073 (Fed. Cir. 1987). Additionaly, the preamble of a claim does not limit the scope of the claim when it merely states intended use of the invention. In re Pearson, 494 F.2d 1399, 1403, 181 USPQ 641, 644 (CCPA 1974). However, terms in a preamble are construed as limitations when they give life and

meaning to the invention claimed. Gerber Garment Technology, Inc. v. Lectra Syst., Inc., 916 F.2d 683, 688, 16 USPQ2d 1436, 1441 (Fed. Cir. 1990) (quoting) Perkins-Elmer Corp. v. Computervision Corp., 732 F.2d 888, 896, 221 USPQ 669, 675 (Fed. Cir.), cert. Denied, 469 U.S. 857 (1984). Although no "litmus test" exists as to what effect should be accorded to terms appearing in a preamble, a patent application in its entirety should be reviewed to determined whether the inventors intended such language to represent additional limitations or mere introductory language. See, e.g., In re Paulsen, 30 F.3d 1475, 1479, 31 USPQ2d 1671, 1673-74 (Fed. Cir. 1994) (Citing Corning Glass Works v. Suitomo Elect. U.S.A., Inc., 868 F.2d 1251, 1257, 9 USPQ2d 1962, 1966 (Fed Cir. 1989).

Accordingly, a review of the specification in Eggers '536, reveals in column 4, lines 63-67, that figure 1 is a perspective view of the electro surgical probe, an electrically conducting liquid supply and an electro surgical power supply. Electrically conducting liquid (50) is shown in figure 1 within an IV bag and in fluid communication with the electro surgical probe (10) as shown in figures 2A and 2B. Moreover, in column 12, lines 26-28, the specification states that electrically conducting liquid (50) (e.g., isotonic saline) is caused to flow along the fluid paths (83).

In view of the foregoing, the phrase "an electrically conducting fluid supply" in the preamble of claim 1, must be interpreted in view of the specification as a limitation disclosing a medical container (e.g., IV bag) that stores electrically conducting liquid

(50) such as isotonic saline. The medical container is in fluid communication with the probe (10) allowing the electrically conducting liquid to make contact with the electrodes at the distal end of the probe (10). Additionally, in the last portion of claim 1, the phrase "the fluid path having an inlet adapted to be fluidly coupled to the electrically conductive fluid supply" unequivocally suggests that the drafter intended the preamble phrase "an electrically conducting fluid supply" to be a structural limitation. Clearly, the phrase "an electrically conducting fluid supply" gives life and meaning to the invention claimed, and therefore, must be considered in the assessment of patentability of claim 1.

Assessment of Patentability

The Roos '198 Patent never describes the use of "electrically conductive fluid" during electrosurgery. The Roos '198 Patent only discloses the use of an unspecified "washing liquid" that flows through the endoscope that houses the treatment and neutral electrodes. See Roos '198 Patent at 4:51-57, Fig. 1. The Roos '198 Patent does not state that the "washing liquid" that is supplied to the region of the surgical site is electrically conductive fluid. This omission is significant, because numerous non-conductive washing liquids, such as distilled water, glycine, sorbitol, and the like, have been used in electrosurgery and are still in use today. See, e.g., U.S. Patent No. 4,936,301 to Rexroth, et al. at 1:62-64 and 2:4-7.

In fact, the Roos '198 specification makes clear that the "washing liquid" delivered to the surgical site in the Roos '198 Patent is not electrically conductive. The

Roos '198 Patent states at column 6, lines 51-53 that "the neutral electrode 11 in the form of a steel band rests on the tissue in large area form, so that good electrical contact is ensured." If the "washing liquid" was electrically conductive, there would be no need for the neutral electrode to rest on the tissue in large area form to ensure good electrical contact. Electrical contact between the neutral electrode and the cutting electrode would be ensured by the "washing liquid" itself. The statement in the Roos '198 Patent that tissue contact with the neutral electrode is needed to ensure electrical contact plainly shows that the "washing liquid" described in the Roos '198 Patent could not have been electrically conductive.

A later-issued patent to the same named inventor, U.S. Patent No. 4,706,667, referenced hereafter as Roos ' 667, demonstrates unequivocally that the "washing liquid" disclosed in the Roos '198 Patent was not electrically conductive. The Roos '198 Patent claims priority to German Patent Application No. 2521719, referenced hereafter as "German Patent Application". The Roos '667 Patent explains at column 1 lines 14-29 that the device described in the German Patent Application (and thus in the Roos '198 Patent) did not work to cut tissue because the medium in contact with the electrodes was not electrically conductive:

"In a known electro-surgical high frequency cutting instrument of this kind (DE-OS No. 25 21 719) the neutral electrode is admittedly arranged in the immediate vicinity of the cutting electrode, it is however so separated from the tissue by a plastic cover, or

by its arrangement in an endoscope, that it can only enter into electrical contact with the cutting electrode electrolytically via the secretion which is present during the cutting process. As a result, it is difficult to maintain the current intensity required for trouble free cutting in a required precisely defined manner at the cutting electrode. Thus, if the power setting at the r.f. generator is too high, burns can result or, if the power setting is too low, then a poor cut or indeed injury occurs because the tissue to be cut sticks to the cutting electrode as a result of coagulation processes".

According to the Roos '667 Patent, the device disclosed in the parent application to the Roos '198 Patent (and thus in the Roos '198 Patent itself) did not work because there was insufficient electrical contact between the neutral and cutting electrodes to cut tissue, even though the electrodes were in the "immediate vicinity" of one another. If the Roos '198 Patent had delivered electrically conducting fluid to the tissue site, such as isotonic saline, then the Roos '667 Patent surely would not have stated, as it did, that the cutting and neutral electrodes "only enter into electrical contact" with each other "via the secretion which is present during the cutting process." If Roos '198 had delivered electrically conducting fluid to the tissue site, there would have been an electrical connection between the cutting and neutral electrodes by virtue of the electrically conducting fluid itself, regardless of whether bodily secretions were present. Plainly, Roos '198 used non-conducting "washing liquid" and attempted to rely on bodily secretions from the cutting process to make the non-conductive "washing liquid" more

conductive. According to the Roos '667 Patent, these secretions did not make the non-conductive "washing liquid" electrically conductive.

Significantly, the Roos '667 Patent did not solve the electrical contact problem described in the Roos '198 Patent by introducing electrically conducting fluid to the tissue site. Rather, the Roos '667 Patent solved the problem of poor conductivity by disclosing a device in which both the cutting and neutral electrodes were in physical contact with the tissue so that current could flow from the cutting electrode, through the tissue, and to the return electrode, not through electrically conducting fluid. The Roos '667 Patent explains at column 4, line 30:

"The instrument is first of all placed in accordance with FIG. 1 onto the tissue 16 which is to be separated by means of a cut, with a concave ring-like contact surface 14 being formed between the tissue 16 and the neutral electrode 11 and with a very small funnel-like contact surface 15 being formed between the tip of the cutting electrode 12 and the tissue 16. If the r.f. generator is now switched on then an r.f. current indicated by the current lines 28 flows between the cutting electrode 12 and the neutral electrode 11".

In conclusion, because the Roos '198 Patent does not disclose or enable electrosurgical ablation in the presence of electrically conductive fluid, it cannot anticipate claims 1, 45, and 63, containing such an element. PPG Indus., Inc. v.

Guardian Indus. Corp., 75 F.3d 1558, 1566 (Fed. Cir. 1996) ("To anticipate a claim, a reference must disclose every element of the challenged claim and enable one skilled in the art to make the anticipating subject matter.").

Section II: References disclosed in the IDS dated June 19, 2002

Claim Rejections

In order to expedite the prosecution of this reexamination, the examiner of record will make direct references to the Supplemental Invalidity Response (Arthrocare Suit-Delaware, USDC-D. DEL.-C.A. No. 01-504-SLR) submitted with the IDS package dated June 19, 2002.

35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily

published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-64 are rejected under 35 U.S.C. 102(b) as being anticipated by O'Malley, et al., reference no. 3. Please refer to page 2 of Supplemental Invalidity Response.

Claims 1-64 are rejected under 35 U.S.C. 102(b) as being anticipated by Curtiss, reference no. 9. Please refer to page 5 of Supplemental Invalidity Response.

Claims 1-64 are rejected under 35 U.S.C. 102(b) as being anticipated by Piercy, et al., reference no. 12. Please refer to page 6 of Supplemental Invalidity Response.

Claims 1-64 are rejected under 35 U.S.C. 102(b) as being anticipated by Dennis, et al., reference number 16. Please refer to page 8 of Supplemental Invalidity Response.

Claims 1-64 are rejected under 35 U.S.C. 102(b) as being anticipated by Barry, et al., reference number 21. Please refer to page 10 of Supplemental Invalidity Response.

Claims 1-64 are rejected under 35 U.S.C. 102(b) as being anticipated by Swain, et al., reference number 24. Please refer to page 12 of Supplemental Invalidity Response.

Claims 1-64 are rejected under 35 U.S.C. 102(b) as being anticipated by Malis, et al., reference number 28. Please refer to page 14 of Supplemental Invalidity Response.

Claims 1-64 are rejected under 35 U.S.C. 102(b) as being anticipated by Pao, reference number 36. Please refer to page 17 of Supplemental Invalidity Response.

Claims 1-64 are rejected under 35 U.S.C. 102(b) as being anticipated by Tucker, et al., reference number 37. Please refer to page 18 of Supplemental Invalidity Response.

Claims 1-64 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee, et al., reference number 38. Please refer to page 18 of Supplemental Invalidity Response.

Claims 1-64 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 90/03152, reference number 43. Please refer to page 21 of Supplemental Invalidity Response.

Claims 1-64 are rejected under 35 U.S.C. 102(b) as being anticipated by Stasz, reference number 46. Please refer to page 22 of Supplemental Invalidity Response.

Claims 1-64 are rejected under 35 U.S.C. 102(b) as being anticipated by Reimels, reference number 52. Please refer to page 25 of Supplemental Invalidity Response.

Claims 1-64 are rejected under 35 U.S.C. 102(b) as being anticipated by Olsen, reference number 57. Please refer to page 28 of Supplemental Invalidity Response.

Claims 1-64 are rejected under 35 U.S.C. 102(b) as being anticipated by Ohtomo, et al., reference number 66. Please refer to page 32 of Supplemental Invalidity Response.

Claims 1-64 are rejected under 35 U.S.C. 102(b) as being anticipated by Rydwell, et al., reference number 67. Please refer to page 32 of Supplemental Invalidity Response.

Claims 1-64 are rejected under 35 U.S.C. 102(b) as being anticipated by Kamerling, reference number 70. Please refer to page 34 of Supplemental Invalidity Response.

Claim Rejections - 35 USC § 103

On page 8 of the Supplemental Invalidity Response, it is alleged that claim 45 of Eggers '536 would have been obvious to one of ordinary skill in the art at the time of the invention in view of at least each of the following combinations. Please refer to the table on pages 1-8 of the Supplemental Invalidity Response to identify the patent/publication number, inventor/author, and title.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> **(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.**

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over any one or more of references 1, 4, 5, 6, 7, 10, 11, 13, 17, 30, 33, 40, 44, 50, 55, 56, 60, 61,

69, 71, 72, 73 in view of any one or more of references 3, 9, 12, 16, 21, 24, 28, 36, 37, 38, 43, 46, 52, 57, 66, 67, 70. According to the allegations of unpatentability disclosed on page 8 of the Supplemental Invalidity Response, it would have been obvious to modify any one or more of references 1, 4, 5, 6, 7, 10, 11, 13, 17, 30, 33, 40, 44, 50, 55, 56, 60, 61, 69, 71, 72, 73 with the enhancements taught by 3, 9, 12, 16, 21, 24, 28, 36, 37, 38, 43, 46, 52, 57, 66, 67, 70, because "each reference is directed to the same problem-Applying electrical energy to a target site on a patient's body structure". Accordingly, all modifications to the base references following the teachings of the secondary references listed above, are considered obvious design choices.

Claims 1-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over any one or more of references 2, 34, and 47, in view of any one or more of references 3, 9, 12, 16, 21, 24, 28, 36, 37, 38, 43, 46, 52, 57, 66, 67, 70. According to the allegations of unpatentability disclosed on page 8 of the Supplemental Invalidity Response, it would have been obvious to modify any one or more of references 2, 34, and 47 with the enhancements taught in references 3, 9, 12, 16, 21, 24, 28, 36, 37, 38, 43, 46, 52, 57, 66, 67, 70, because "each reference is directed to the same problem-Applying electrical energy to a target site on a patient's body structure". Accordingly, all modifications to the base references following the teachings of the secondary references listed above, are considered obvious design choices.

Claims 1-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over reference 59 in view of any one or more of references 3, 9, 12, 16, 21, 24, 28, 36, 37, 38, 43, 46, 52, 57, 66, 67, 70. According to the allegations of unpatentability disclosed on page 9 of the Supplemental Invalidity Response, it would have been obvious to modify reference 59 with the enhancements taught in references 3, 9, 12, 16, 21, 24, 28, 36, 37, 38, 43, 46, 52, 57, 66, 67, 70, because "each reference is directed to the same problem-Applying electrical energy to a target site on a patient's body structure". Accordingly, all modifications to the base references following teachings of the secondary references listed above are considered obvious design choices.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manuel Mendez whose telephone number is 703-308-2221. The examiner can normally be reached on 0730-1800 hrs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Brian Casler can be reached on 703-308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

September 24, 2002

Manuel Mendez
Primary Examiner
Art Unit 3763

Paper #10

FORM PTO-1449 (Modified) LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)	Attorney Docket No. 16238-000610	Patent No.: 5,697,536
	Applicant: PHILIP E. EGGERS et al.	
	Issue Date: December 16, 1997	Group:

Reference Designation

U.S. PATENT DOCUMENTS

Examiner Initial	Document No.	Date	Name	Class	Sub-class	Filing Date
AA	4,682,596	07/28,1987	Bales et al.	128	303	
AB	5,514,130	05/07/96	Baker	606	41	
AC	5,078,717	01/07/92	Parins et al.	606	48	
AD	5,697,281	12/16/97	Eggers et al.	604	114	
AE	5,697,882	12/16/97	Eggers et al.	604	114	
AF	5,697,909	12/16/97	Eggers et al.	604	114	
AG	5,725,524	03/10/98	Mulier et al.	606	41	
AH	5,609,151	03/11/97	Mulier et al.	128	642	
AI	4,043,342	08/23/97	Morrison, Jr.	128	303	
AJ	4,184,492	01/22/80	Meinke et al.	128	303	
AK	4,248,231	02/03/81	Herczog et al.	128	303	

FOREIGN PATENT DOCUMENTS

	Document No.	Date	Country	Class	Sub-class	Translation (yes/no)
AL	97/00647	01/09/97	WIPO	A61B	17/39	
AM	97/00646	01/09/97	WIPO	A61B	17/39	
AN	EP 0 703 461	03/27/96	Europe	G01R	27/02	
AO	EP 0 754 437	01/22/97	Europe	A61B	17/39	
AP	93/20747	10/28/93	WIPO	A61B	5/00	
AQ	97/48345	12/24/97	WIPO	A61B	17/39	
AR	98/27880	07/02/98	WIPO	A61B	17/39	

OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

AS	Pearce, John A. (1986) *Electrosurgery*, pgs. 17, 69-75, 87, John Wiley & Sons, New York.
AS1	V. E. Elsasser et al. *Acta Medicotechnica* Vol. 24, No. 4, pp. 129-134 (1976).

EXAMINER [signature] DATE CONSIDERED April 29, 2002

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449 (Modified) LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)	Attorney Docket No. 16238-000610	Patent No.: *5,697,536*
	Applicant: PHILIP E. EGGERS et al.	
	Issue Date: *December 16, 1997*	Group:

Reference Designation

U.S. PATENT DOCUMENTS

Examiner Initial	Document No.	Date	Name	Class	Sub-class	Filing Date
AT	4,706,667	11/17/87	Roos	128	303	
AU	5,584,872	12/17/96	LaFontaine et al.	607	117	
AV	5,676,693	10/14/97	LaFontaine et al.	607	116	
AW	5,370,675	12/06/94	Edwards et al.	607	101	
AX	5,080,660	01/14/92	Buelna	606	45	
AY	5,417,687	05/23/95	Nardella et al.	606	32	
AZ	4,232,676	11/11/80	Herczog	128	303	
BA	4,033,351	07/05/77	Hetzel	128	303	
BB	5,112,330	05/12/92	Nishigaki et al.	606	46	
BC	5,843,019	12/01/98	Eggers et al.	604	22	
BD	5,871,469	02/16/99	Eggers et al.	604	114	
BE	5,007,908	04/16/91	Rydell	606	47	

FOREIGN PATENT DOCUMENTS

	Document No.	Date	Country	Class	Sub-class	Translation (yes/no)
BF	2 327 350	01/27/99	UK	A61B	17/39	
BG	2 327 351	01/27/99	UK	A61B	17/39	
BH	2 327 352	01/27/99	UK	A61B	17/39	
BI	WO95/34259	12/21/95	WIPO	A61F	5/48	
BJ	57-57802	04/05/82	JP	A61B	1/00	

OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

BK	Buchelt, M. et al. "Excimer Laser Ablation of Fibrocartilage: An In Vitro and In Vivo Study," (1991) LASERS IN SURGERY AND MEDICINE 11:271-279.
BL	Costello, A. J. et al. "Nd:YAG Laser Ablation of the Prostate as a Treatment of Benign Prostatic Hypertrophy," (1992) LASERS IN SURGER AND MEDICINE 12:121-124.

EXAMINER [signature] DATE CONSIDERED April 29, 2002

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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	Applicant: PHILIP E. EGGERS et al.	
	Issue Date: December 16, 1997	Group: 3739

OIPE JC103 OCT 16 2001 PATENT & TRADEMARK OFFICE

Reference Designation

U.S. PATENT DOCUMENTS

Examiner Initial	Document No.	Date	Name	Class	Sub-class	Filing Date
BM	5,192,280	03/09/93	Parins	606	48	
BN	5,662,680	09/02/97	Desai	606	210	
BO	5,249,585	10/05/93	Turner et al.	607	99	
BP	5,190,517	03/02/93	Zieve et al.	604	22	
BQ	5,366,443	11/22/94	Eggers et al.	604	114	
BR	5,122,138	06/16/92	Manwaring	606	46	
BS	5,330,470	07/19/94	Hagen	606	42	
BT	5,647,869	07/15/97	Goble et al.	606	37	
BU	4,040,426	08/09/77	Morrison, Jr.	128	303	
BV	4,548,207	10/22/85	Reimels	128	303	
BW	4,823,791	04/25/89	D'Amelio et al.	123	303	
BX	5,098,431	03/24/92	Rydell	606	48	
BY						

FOREIGN PATENT DOCUMENTS

	Document No.	Date	Country	Class	Sub-class	Translation (yes/no)
BZ	WO 94/04220	03.03.94	WIPO	yes	A61N	1/06
CA	97/24073	07/10/97	WIPO	A61B	17/39	
CB	97/24993	07/17/97	WIPO	A61B	17/39	
CC	97/24994	07/17/97	WIPO	A61B	17/39	
CD	97/48346	12/24/97	WIPO	A61B	17/39	
CE	96/00042	01/04/96	WIPO	A61B	17/39	

OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

CF	J.W. Ramsey et al. *Urological Research* Vol. 13, pp. 99-102 (1985).
CG	Slager et al. *JACC* 5(6):1382-6 (1985).

EXAMINER [signature] DATE CONSIDERED April 29, 2002

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449 (Modified) LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)	Attorney Docket No. 16238-000610	Patent No.: 5,697,536
	Applicant: PHILIP E. EGGERS et al.	
	Issue Date: *December 16, 1997*	Group: 3739

Reference Designation

U.S. PATENT DOCUMENTS

Examiner Initial	Document No.	Date	Name	Class	Sub-class	Filing Date
CH	5,217,457	06/08/93	Delahuerga et al.	606	42	
CI	4,240,441	12/23/80	Khalil	128	692	
CJ	5,197,963	03/30/93	Parins	606	46	
CK	5,944,715	08/31/99	Goble et al.	606	41	
CL	5,057,106	10/15/91	Kasevich et al.	606	33	
CM	4,860,752	08/29/89	Turner	128	422	
CN	5,807,395	09/15/98	Mulier et al.	606	41	
CO	5,700,262	12/23/97	Acosta et al.	606	48	
CP	5,441,499	08/15/95	Fritzsch	606	45	
CQ	5,035,696	07/30/91	Rydell	606	47	
CR	5,749,869	05/12/98	Lindenmeier et al.	606	34	
CS	5,267,997	12/07/93	Farin et al.	606	38	
CT	5,281,218	01/25/94	Imran	606	41	
CU	5,125,928	06/30/92	Parins et al.	606	48	
CV	5,496,312	03/05/96	Klicek	606	34	

FOREIGN PATENT DOCUMENTS

	Document No.	Date	Country	Class	Sub-class	Translation (yes/no)
CW	98/07468	02/26/98	WIPO	A61N	1/40	
CX	2 308 981	07/16/97	GB	A61B	17/36	
CY	2 308 980	07/16/97	GB	A61B	17/36	
CZ	2 308 979	07/16/97	GB	A61B	17/36	

OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

DA	R. Tucker et al., Abstract P14-11, p. 248, "A Bipolar Electrosurgical Turp Loop"
DB	R. Tucker et al, *J. of Urology* Vol. 141, pp. 662-665, (1989).
DC	R. Tucker et al. *Urological Research* Vol. 18, pp. 291-294 (1990).

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FORM PTO-1449 (Modified) LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)	Attorney Docket No. 16238-000610	Patent No.: *5,697,536*
	Applicant: PHILIP E. EGGERS et al.	
	Issue Date: *December 16, 1997*	Group: 3739

OCT 1 6 2001 TC 1600/2900 PATENT & TRADEMARK OFFICE

Reference Designation — **U.S. PATENT DOCUMENTS**

Examiner Initial	Document No.	Date	Name	Class	Sub-class	Filing Date
DD	5,810,809	09/22/98	Rydell	606	49	
DE	5,800,431	09/01/98	Brown	606	42	
DF	5,885,277	03/23/99	Korth	606	35	
DG	6,068,628	05/30/00	Fanton et al.	606	41	
DH	6,238,391	05/29/01	Olsen et al.	606	41	
DI	6,254,600	07/03/01	Willink et al.	606	41	
DJ	6,264,652	07/24/01	Eggers et al.	606	41	
DK	6,013,076	01/11/00	Goble et al.	606	41	
DL	6,015,406	01/18/00	Goble et al.	606	41	
DM	6,027,501	02/22/00	Goble et al.	606	41	
DN	6,004,319	12/21/99	Goble et al.	606	48	
DO	6,039,734	03/21/00	Goble et al.	606	41	
DP	6,056,746	05/02/00	Goble et al.	606	48	
DQ	6,093,186	07/25/00	Goble et al.	606	34	
DR	6,074,386	06/13/00	Goble et al.	606	34	
DS	6,090,106	07/18/00	Goble et al.	606	41	

FOREIGN PATENT DOCUMENTS

	Document No.	Date	Country	Class	Sub-class	Translation (yes/no)
DT	98/27879	07/02/98	WIPO	A61B	17/36	
DU	57-117843	07/22/82	JP	A61B	17/39	
DV	99/51158	10/14/99	WIPO	A61B	17/39	

OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

DW	Kramolowsky et al. *J. of Urology* Vol. 143, pp. 275-277 (1990).
DX	Kramolowsky et al. *J. of Urology* Vol. 146, pp. 669-674 (1991).
DY	Slager et al. *J. Kardiol.* 76:Suppl. 6, 67-71 (1987).

EXAMINER [signature] DATE CONSIDERED Apr 29, 2002

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FORM PTO-1449 (Modified) LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)	Attorney Docket No. 16238-000610	Patent No.: *5,697,536*
	Applicant: PHILIP E. EGGERS et al.	
	Issue Date: *December 16, 1997*	Group: 3739

Reference Designation

U.S. PATENT DOCUMENTS

Examiner Initial	Document No.	Date	Name	Class	Sub-class	Filing Date
DZ	5,681,282	10/28/97	Eggers et al.	604	114	
~~EA~~						
EB	5,766,153	06/16/98	Eggers et al.	604	114	
EC	5,810,764	09/22/98	Eggers et al.	604	23	
ED	5,683,366	11/04/97	Eggers et al.	604	114	
EE	4,727,874	03/01/88	Bowers et al.	128	303	
EF	5,318,563	06/07/94	Malis et al.	606	38	
EG	5,556,397	09/17/96	Long et al.	606	48	
EH	5,897,553	04/27/99	Mulier	606	41	
EI	5,888,198	03/30/99	Eggers et al.			
EJ	5,891,095	04/06/99	Eggers et al.			
EK	5,902,272	05/11/99	Eggers et al.			
~~EL~~						
~~EM~~						
~~EN~~						
EO	6,224,592	05/01/01	Eggers et al.	606	32	

FOREIGN PATENT DOCUMENTS

	Document No.	Date	Country	Class	Sub-class	Translation (yes/no)
EP	99/51155	10/14/99	WIPO	A61B	17/36	
~~EQ~~						

OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

EXAMINER [signature] DATE CONSIDERED April 29, 2002

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Paper #11

FORM PTO-1449 (Modified) LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)	Attorney Docket No. 16238-000610	Patent No.: *5,697,536*
	Applicant: PHILIP E. EGGERS et al.	
	Issue Date: *December 16, 1997*	Group:

Reference Designation — U.S. PATENT DOCUMENTS

Examiner Initial	Document No.	Date	Name	Class	Sub-class	Filing Date
	2,056,377	08/16/33	Wappler	128	303.14	
	3,815,604	06/11/74	O'Malley et al.	128	305	
	3,828,780	08/13/74	Morrison Jr.	128	275.1	
	3,901,242	08/26/75	Storz	128	303.15	
	3,920,021	11/18/75	Hiltebrandt	128	303.17	
	3,939,839	02/24/76	Curtiss	128	303.15	
	3,970,088	07/20/76	Morrison	128	303.14	
	4,074,718	02/21/78	Morrison, Jr.	128	303.14	
	4,181,131	01/01/80	Ogiu	128	303.15	
	4,590,934	05/27/86	Malis et al.	128	303.14	
	4,660,571	04/28/87	Hess et al.	128	784	
	4,785,823	11/22/88	Eggers et al.	128	692	
	4,805,616	02/21/89	Pao	128	303.17	
	4,832,048	05/23/89	Cohen	128	786	
	4,920,978	05/01/90	Colvin	128	784	
	4,936,281	06/26/90	Stasz	128	660.03	
	4,966,597	10/30/90	Cosman	606	50	
	5,009,656	04/23/91	Reimels	606	48	
	5,047,026	09/10/91	Rydell	606	48	
	5,047,027	09/10/91	Rydell	606	48	
	5,084,044	01/28/92	Quint	606	27	
	5,085,659	02/04/92	Rydell	606	47	
	5,088,997	02/18/92	Delahuerga et al.	606	42	
	5,167,659	12/01/92	Ohtomo et al.	606	40	
	5,171,311	12/15/92	Rydell et al.	606	48	
	5,207,657	05/04/93	Canady	606	40	
	5,217,459	06/08/93	Kamerling	606	48	
	5,306,238	04/26/94	Fleenor	606	42	
	5,423,882	06/13/95	Jackman et al.	607	127	
	5,454,809	10/03/95	Janssen	606	41	

September 19, 2002

FORM PTO-1449 (Modified) LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)	Attorney Docket No. 16238-000610	Patent No.: *5,697,536*
	Applicant: PHILIP E. EGGERS et al.	
	Issue Date: *December 16, 1997*	Group:

FOREIGN PATENT DOCUMENTS

Examiner Initial	Document No.	Date	Name			Translation (yes/no)
	2 313 949/ N 76 17587	01/07/77	Hiltebrandt et al.			Yes
	WO 90/03152	04/05/90	Considine et al.			
	DE 3930451 A1	03/21/91	Hoffman et al.			Yes

OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	Dobie, A. K., *Bio-Medical Engineering*, 05/69, pp. 206-216, "The Electrical Aspects of Surgical Diathermy"
	Honig, William M., *IEEE Transactions on Biomedical Engineering*, "The Mechanism of Cutting in Electrosurgery"
	Piercy M.D., J. R. A., *Gastroenterology* V74, no. 3, pp. 527-534, 1978, "Electrosurgical Treatment of Experimental Bleeding Canine Gastric Ulcers: Development and Testing of a Computer Control and a Better Electrode"
	Dennis, M. B., *Digestive Diseases and Sciences*, V24, no. 11, pp. 845-848, "Evolution of Electrofulguration in Control of Bleeding of Experimental Gastric Ulcers"
	Barry, Kevin J., *CRC Press, American Heart Journal*, V117, pp. 332-341, "The effect of radiofrequency generated thermal energy on the mechanical and histologic characteristics of the arterial wall in vivo: Implications for radiofrequency angioplasty"
	Swain, CP, *Gut* V25, pp. 1424-1431, "Which Electrode?, A comparison of four endoscopic methods of electrocoagulation in experimental bleeding ulcers"
	Tucker, Robert D., *Journal of Urology*, V141 pp662-665, "A Comparison of Urologic Application of Bipolar Versus Monopolar Five French Electrosurgical Probes"
	Lee, Benjamin I., *JACC* V13, no. 5, pp. 1167-1175, "Thermal Compression an Molding of Atherosclerotic Vascular Tissue with Use of Radiofrequency Energy: Implications for Radiofrequency Balloon Angioplasty"
	Olsen MD, Bipolar Laparoscopic Cholecstectomy Lecture (marked confidential), 10/07/91

EXAMINER [signature] DATE CONSIDERED September 19 2002

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Atty Docket No. 16238-000610

PTO FAX NO.: 1 (703) 746-9251
Attn.: **Examiner M. Mendez**
Art Unit: 3739

CERTIFICATION OF FACSIMILE TRANSMISSION

I hereby certify that the following Information Disclosure Statement and PTO-1449 in re Application of Philip E. Eggers et al., Reexamination No. 90/005,601, for SYSTEM AND METHOD FOR ELECTROSURGICAL CUTTING AND ABLATION is being facsimile transmitted to the Patent and Trademark Office on the date shown below.

Number of pages being transmitted, including this page: 180

Dated: June 19, 2002

Katie Zarzana

I hereby certify that this correspondence is being transmitted via facsimile to the Patent and Trademark Office at (703) 746-9251 addressed to:

Examiner Manuel Mendez

Assistant Commissioner for Patents,
Washington, D.C. 20231

On 6/17/02

By _____
Katie Zarzana

PATENT

Attorney Docket No.: 16238-000610

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of:

PHILIP E. EGGERS et al.

Application No. 90/005,601

Reexamination of Patent No.: 5,697,536

Issued: December 16, 1997

For: SYSTEM AND METHOD FOR ELECTROSURGICAL CUTTING AND ABLATION

Examiner: M Mendez

Art Unit: 3739

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §1.97 and §1.98

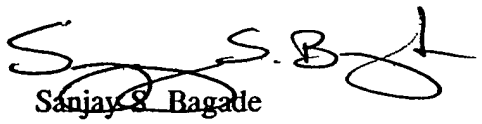
Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

The references cited on attached form PTO-1449 are being called to the attention of the Examiner. These references were brought to Applicant's attention through the *Smith & Nephew* litigation referred to in the previously submitted IDS. Also being submitted are the following documents provided by the defendant, *Smith & Nephew*, in the aforementioned litigation :

i) Ten pages from Smith & Nephew's supplemental invalidity response regarding the reexamination patent at issue (pages 1-9 and a cover page dated June 3, 2002).

ii) 36 pages of "Exhibit A" from Smith & Nephew's supplemental invalidity response. Applicant notes that this document refers to Reference nos. 1-13, 15-31, 33-62, and 64-73 (Reference nos. 14, 32, and 63 are omitted). The Smith & Nephew's supplemental invalidity response cross references these Reference Nos. to the publication information. Applicant notes that Reference nos. 8, 15, 18, 19, 20, 22, 23, 25-27, 29, 31, 34, 35, 39, 41, 42, 45, 48, 49, 51, 53, 54, 58, 62, 64, 65, and 68 were previously considered during either reexamination or prosecution of the patent and are not included in this IDS.



Sanjay S. Bagade
Reg. No. 42,280

ArthroCare Corporation
680 Vaqueros Ave.
Sunnyvale, CA 94085
(408) 736-0224

FORM PTO-1449 (Modified) LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)	Attorney Docket No. 16238-000610	Patent No.: *5,697,536*
	Applicant: PHILIP E. EGGERS et al.	
	Issue Date: *December 16, 1997*	Group:

Reference Designation **U.S. PATENT DOCUMENTS**

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	2,056,377	08/16/33	Wappler	128	303.14	
	3,815,604	06/11/74	O'Malley et al.	128	305	
	3,828,780	08/13/74	Morrison Jr.	128	275.1	
	3,901,242	08/26/75	Storz	128	303.15	
	3,920,021	11/18/75	Hiltebrandt	128	303.17	
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	4,805,616	02/21/89	Pao	128	303.17	
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	5,085,659	02/04/92	Rydell	606	47	
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	5,167,659	12/01/92	Ohtomo et al.	606	40	
	5,171,311	12/15/92	Rydell et al.	606	48	
	5,207,657	05/04/93	Canady	606	40	
	5,217,459	06/08/93	Kamerling	606	48	
	5,306,238	04/26/94	Fleenor	606	42	
	5,423,882	06/13/95	Jackman et al.	607	127	
	5,454,809	10/03/95	Janssen	606	41	

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	Applicant: PHILIP E. EGGERS et al.	
	Issue Date: *December 16, 1997*	Group:

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	WO 90/03152	04/05/90	Considine et al.			
	DE 3930451 A1	03/21/91	Hoffman et al.			Yes

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	Honig, William M., *IEEE Transactions on Biomedical Engineering*, "The Mechanism of Cutting in Electrosurgery"
	Piercy M.D., J. R. A., *Gastroenterology* V74, no. 3, pp. 527-534, 1978, "Electrosurgical Treatment of Experimental Bleeding Canine Gastric Ulcers: Development and Testing of a Computer Control and a Better Electrode"
	Dennis, M. B., *Digestive Diseases and Sciences*, V24, no. 11, pp. 845-848, "Evolution of Electrofulguration in Control of Bleeding of Experimental Gastric Ulcers"
	Barry, Kevin J., *CRC Press, American Heart Journal*, V117, pp. 332-341, "The effect of radiofrequency generated thermal energy on the mechanical and histologic characteristics of the arterial wall in vivo: Implications for radiofrequency angioplasty"
	Swain, CP, *Gut* V25, pp. 1424-1431, "Which Electrode?, A comparison of four endoscopic methods of electrocoagulation in experimental bleeding ulcers"
	Tucker, Robert D., *Journal of Urology*, V141 pp662-665, "A Comparison of Urologic Application of Bipolar Versus Monopolar Five French Electrosurgical Probes"
	Lee, Benjamin I., *JACC* V13, no. 5, pp. 1167-1175, "Thermal Compression an Molding of Atherosclerotic Vascular Tissue with Use of Radiofrequency Energy: Implications for Radiofrequency Balloon Angioplasty"
	Olsen MD, Bipolar Laparoscopic Cholecstectomy Lecture (marked confidential), 10/07/91

EXAMINER	DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

CERTIFICATE OF SERVICE

I hereby certify that on this 1st day of October 2002, a true and correct copy of the document listed below was caused to be served on the attorneys of record at the following addresses as indicated:

1. Information Disclosure Statement and Form PTO-1449 (dated 06/17/02)

BY U.S. POSTAL SERVICE
FIRST CLASS MAIL

William C. Fuess
FUESS & DAVIDENAS
10951 Sorrento Valley Road, Suite II-G
San Diego, CA 92121-1613

Executed on October 1, 2002 at Sunnyvale, California.

Katie Zarzana

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to:

Assistant Commissioner for Patents,
Washington, D.C. 20231

On Oct. 17, 2001

By _____
Katie Zarzana

PATENT

Attorney Docket No.: 16238-000610

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of:

PHILIP E. EGGERS et al.

Application No. 90/005,601

Reexamination of Patent No.: 5,697,536

Issued: December 16, 1997

For: SYSTEM AND METHOD FOR ELECTROSURGICAL CUTTING AND ABLATION

Examiner: M Mendez

Art Unit: 3739

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §1.97 and §1.98

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

The references cited on attached form PTO-1449 are being called to the attention of the Examiner. A copy of each is enclosed.

The Owner, ArthroCare Corporation, also brings the following information and list of materials to the attention of the Examiner. On February 13, 1998, ArthroCare Corporation filed a lawsuit in the United States District Court for the Northern District of California against defendants Ethicon, Inc., Mitek Surgical Products, Inc., and Gynecare, Inc., alleging infringement of U.S. Patent Nos. 5,697,909, 5,697,536, 5,697,281, and 5,697,882 (the "patents-in-suit"). The case was assigned Case No. C98-00609 WHO (the "*Ethicon* litigation"). The *Ethicon* litigation terminated in June 1999, with the defendants taking a license from ArthroCare under the patents-in-suit. The defendants have paid ArthroCare a license fee, and will pay ongoing royalties on sales in the United States of certain arthroscopy and gynecology products covered by these patents.

After the *Ethicon* litigation terminated, Owner was apprised by a third party of section 2001.06(c) of the Manual of Patent Examining Procedure ("MPEP") with respect to the prosecution of applications for patents other than those at issue in the *Ethicon* litigation and that were pending before the

Ethicon litigation was commenced, namely, U.S. Application Nos. 08/807,111 (now U.S. Patent No. 5,891,095), 08/766,382 (now U.S. Patent No. 5,888,198), and 08/760,768 (now U.S. Patent No. 5,766,153).

Although not required to do so, Owner did bring the *Ethicon* litigation to the attention of Examiner Mendez during the prosecution of at least U.S. Application Nos. 08/807,111 (now U.S. Patent No. 5,891,095), 08/766,382 (now U.S. Patent No. 5,888,198), and 08/795,686 (now U.S. Patent No. 5,871,469), during a telephone conference relating to those applications. Owner also submitted the prior art that was principally relied on by the defendants in the *Ethicon* litigation to Examiner Mendez during the prosecution of U.S. Application Nos. 08/807,111 (now U.S. Patent No. 5,891,095), 08/766,382 (now U.S. Patent No. 5,888,198), and 08/795,686 (now U.S. Patent No. 5,871,469). Indeed, Owner withdrew one of those pending applications, namely, U.S. Application No.08/807,111 (now U.S. Patent No. 5,891,095), from allowance to provide Examiner Mendez with the opportunity to consider those references.

Accompanying this statement is a form listing references for the Examiner's consideration in connection with the present reexamination, including references principally relied on by the defendants in the *Ethicon* litigation.

In addition, Owner provides the following list of materials from the *Ethicon* litigation that reflect the defendants' and ArthroCare's primary arguments relating to issues of validity and enforceability:

1. ArthroCare's Complaint For Patent Infringement Of U.S. Letters Patent Nos. 5,697,909; 5,697,281; 5,697,882; and 5,697,536 filed February 13, 1998;
2. Plaintiff ArthroCare's Motion For Preliminary Injunction Against Defendant Ethicon and Mitek, filed March 10, 1998.
3. Answer and Counterclaim Of Defendants Ethicon, Inc., Mitek Surgical Products, Inc., and Gynecare, Inc., filed April 6, 1998;
4. Plaintiff ArthroCare's Motion To Strike Affirmative Defenses And To Strike Defendants' Counterclaim In Part Or, In The Alternative, For a More Definite Statement, filed April 17, 1998;
5. Defendants' Opposition To ArthroCare's Motion To Strike Affirmative Defenses And To Strike Defendants' Counterclaim In Part Or, In The Alternative For A More Definite Statement And Points

And Authorities In Support Of Conditional Motion To File An Amended Answer and Counterclaim, filed May 7, 1998;

6. ArthroCare's Reply In Support of Motion To Strike Affirmative Defenses And To Strike Defendants' Counterclaim In Part Or, In The Alternative, For A More Definite Statement, filed May 14, 1998;
7. Memorandum Decision And Order Regarding ArthroCare's Motion To Strike And Defendants' Motion For Leave To File An Amended Answer And Counterclaim, issued June 5, 1998;
8. Amended Answer And Counterclaim of Defendants Ethicon, Inc., Mitek Surgical Products, Inc., and Gynecare, Inc., filed June 22, 1998;
9. ArthroCare's Reply to Defendants' Amended Counterclaim, filed July 6, 1998;
10. ArthroCare's Initial Disclosure Of Asserted Claims Pursuant To Local Rule 16-7, served March 30, 1998;
11. Defendants' Initial Disclosure of Prior Art Pursuant To Local Rule 16-7, served May 26, 1998;
12. Plaintiff ArthroCare's Corporation's Opening Claim Construction Brief, filed May 11, 1998;
13. Ethicon, Inc.'s Claim Construction Brief, filed May 22, 1998;
14. Joint Claim Construction Statement Pursuant To Civil Local Rule 16-11(b)(1) For Claim Construction Hearing, filed May 29, 1998;
15. Plaintiff ArthroCare's Corporation's Reply To Defendants' Claim Construction Brief, filed May 29, 1998;
16. Memorandum Decision And Order Regarding Claim Construction, issued July 6, 1998;
17. Defendants' Petition For Permission To Appeal Pursuant To 28 U.S.C. §1292(b) filed with the U.S. Court of Appeals for the Federal Circuit on July 16, 1998;
18. Plaintiff's Answer To Defendants' petition For Permission To Appeal Pursuant To 28 U.S.C. §1292(b), filed July 23, 1998;
19. Federal Circuit's Order On Petition For Permission To Appeal, issued August 20, 1998;
20. Summary Of Defendant Ethicon's Opposition To Plaintiff ArthroCare's Motion For Preliminary Injunction, filed July 23, 1998;
21. Ethicon's Opposition To Plaintiff ArthroCare's Motion For Preliminary Injunction, filed July 23, 1998;

22. Declaration Of John R. LaCourse In Opposition To ArthroCare's Motion For Preliminary Injunction, filed July 23, 1998;
23. Declaration Of Robert D. Tucker Filed In Support Of Ethicon's Opposition To ArthroCare's Motion For Preliminary Injunction, filed July 23, 1998;
24. Declaration Of Robert A. Armitage, Esq., Filed In Support Of Ethicon's Opposition To ArthroCare's Motion For Preliminary Injunction , filed July 23, 1998;
25. Supplemental Declaration Of Robert A. Armitage, Esq., In Support of Ethicon's Opposition To Plaintiff ArthroCare's Motion For Preliminary Injunction, filed August 4, 1998;
26. ArthroCare's Reply Memorandum In Support Of Motion For Preliminary Injunction, filed August 6, 1998;
27. Declaration Of James Doss In Support Of ArthroCare's Motion For Preliminary Injunction, filed August 6, 1998;
28. Reply Declaration Of Philip E. Eggers In Support Of ArthroCare's Motion For Preliminary Injunction, filed August 6, 1998;
29. Reply Declaration Of John T. Raffle In Support Of ArthroCare's Motion For Preliminary Injunction, filed August 6, 1998;
30. Ethicon's Supplemental Opposition To Plaintiff ArthroCare's Motion For Preliminary Injunction, filed September 3, 1998.
31. Supplemental Declaration Of Robert D. Tucker, Ph.D. M.D., Filed In Support Of Ethicon's Opposition To ArthroCare's Motion For Preliminary Injunction, filed September 3, 1998;
32. Supplemental Declaration Of John R. LaCourse, Ph.D., Filed In Support Of Ethicon's Opposition To ArthroCare's Motion For Preliminary Injunction, filed September 3, 1998;
33. Direct Examination Of Robert D. Tucker, Ph.D., M.D., Filed In Support Of Ethicon's Opposition To ArthroCare's Motion For Preliminary Injunction; filed September 3, 1998;
34. Direct Examination of Robert A. Armitage, Esq., Filed In Support Of Ethicon's Opposition To ArthroCare's Motion For Preliminary Injunction, filed September 3, 1998;
35. Direct Examination of John R. LaCourse, Ph.D., Filed In Support of Ethicon's Opposition To ArthroCare's Motion For Preliminary Injunction, filed September 3, 1998;

36. ArthroCare's Supplemental Memorandum In Response To The Supplemental Declaration Of Robert A. Armitage, filed September 3, 1998;
37. Direct Testimony Of John T. Raffle In Support Of ArthroCare's Motion For Preliminary Injunction, filed September 3, 1998;
38. Direct Testimony Of Philip E. Eggers In Support Of ArthroCare's Motion For Preliminary Injunction, filed September 3, 1998;
39. Joint Statement Regarding Differences Between The Two Translations Of The Elsasser And Roos Article Proffered By Defendants, filed September 22, 1998;
40. Memorandum Decision And Order Regarding Preliminary Injunction Motion, issued December 2, 1998;
41. Ethicon's Response To ArthroCare's First Set of Interrogatories To Defendant Ethicon, served November 6, 1998;
42. Plaintiff ArthroCare's Response To Defendant Gynecare, Inc.'s First Set Of Interrogatories, served November 10, 1998;
43. Plaintiff ArthroCare's Response To Mitek's First Set Of Interrogatories, served November 10, 1998;
44. Plaintiff ArthroCare's Response To Defendant Ethicon, Inc.'s First Set of Interrogatories, served November 10, 1998;
45. Plaintiff ArthroCare's Objections And Responses To Defendants' First Set Of Requests For Admissions, served January 4, 1999;
46. Plaintiff ArthroCare's Objections and Responses To Defendant Gynecare, Inc.'s Second Set Of Interrogatories, served January 4, 1999;
47. Plaintiff ArthroCare's Supplemental Objections and Responses to Defendants' Request For Admission No. 36, served January 5, 1999;
48. Expert Witness Report of John R. LaCourse, served January 8, 1999;
49. Expert Witness Report of Robert D. Tucker, served January 8, 1999;
50. Expert Witness Report of David J. Parins, served January 8, 1999;
51. Expert Witness Report of Robert A. Armitage, Esq., served January 8, 1999;
52. Expert Witness Report of Massoud Motamedi, Ph.D., served January 8, 1999;
53. Expert Witness Report of Ashley J. Welch, Ph.D., served January 8, 1999;

54. Responsive Expert Report of Leslie A. Geddes, Ph.D., served January 29, 1999;

55. Responsive Expert Report of Donald W. Banner served January 29, 1999;

56. Supplemental Expert Report of David J. Parins served February 9, 1999;

57. Ethicon's Motion For Summary Judgment Of Invalidity For Failure To Satisfy The Requirements of 35 U.S.C. §§102-103, filed March 5, 1999;

58. Joint Statement Of Uncontested Facts In Support Of Ethicon's Motion For Partial Summary Judgment Of Invalidity Under 35 U.S.C. §§102 and 103, filed March 5, 1999;

59. Plaintiff ArthroCare's Opposition To Defendants' Motion For Summary Judgment Of Invalidity Under 35 U.S.C. §§102-103, filed March 18, 1999;

60. Ethicon's Reply Memorandum In Support Of Motion For Summary Judgment Of Invalidity Under 35 U.S.C. §§102 and 103, filed March 25, 1999;

61. Ethicon's Motion For Partial Summary Judgment Of Invalidity For Failure To Satisfy The Requirements of 35 U.S.C. §112, filed March 5, 1999;

62. Joint Statement Of Uncontested Facts In Support of Ethicon's Motion For Partial Summary Judgment For Invalidity For Failure To Satisfy The Requirements Of 35 U.S.C. §112, filed March 5, 1999;

63. Plaintiff ArthroCare's Opposition To Defendants' Motion For Partial Summary Judgment Of Invalidity For Failure To Satisfy The Requirements Of 35 U.S.C. §112, filed March 18, 1999;

64. Ethicon's Reply Memorandum In Support Of Motion For Partial Summary Judgment Of Invalidity For Failure To Satisfy The Requirements Of 35 U.S.C. §112, filed March 25, 1999;

65. Declaration of Leslie A. Geddes, Ph.D., In Support of ArthroCare's Oppositions To Defendants Motions For Partial Summary Judgment, filed March 18, 1999;

66. Plaintiff ArthroCare's Motion For Partial Summary Judgment That Claims Are Not Anticipated Or Rendered Obvious By Certain References, filed March 5, 1999;

67. Ethicon's Opposition To ArthroCare's Motion For Partial Summary Judgment That Claims Are Not Anticipated Or Rendered Obvious By Certain References, filed March 18, 1999;

68. ArthroCare's Reply Brief In Support Of ArthroCare's Motion For Partial Summary Judgment That Claims Are Not Anticipated Or Rendered Obvious By Certain References, filed March 25, 1999;

69. Plaintiff ArthroCare's Motion For Partial Summary Judgment Of No Inequitable Conduct Or, Alternatively, For Bifurcation, filed March 5, 1999;

70. Joint Statement Of Undisputed Facts In Support Of ArthroCare's Motion For Partial Summary Judgment Of No Inequitable Conduct Or, Alternatively, For Bifurcation, filed March 5, 1999;
71. Ethicon's Opposition Of Plaintiff ArthroCare's Motion For Partial Summary Judgment Of No Inequitable Conduct Or Alternatively For Bifurcation, filed March 18, 1999;
72. Declaration of Robert A. Armitage, Esq., In Support Of Defendant Ethicon, Inc.'s Opposition To ArthroCare's Motion For Summary Judgment, filed March 18, 1999;
73. Plaintiff ArthroCare's Reply Brief In Support Of Its Motion For Partial Summary Judgment Of No Inequitable Conduct Or, Alternatively, For Bifurcation, filed March 25, 1999;
74. Plaintiff ArthroCare's Motion For Partial Summary Judgment That Defendants Cannot Prevail On Their Enablement And Written Description Defenses As To Certain Claims, filed March 5, 1999;
75. Joint Statement Of Undisputed Facts In Support Of ArthroCare's Motion For Partial Summary Judgment That Defendants Cannot Prevail Under Enablement And Written Description Defenses As To Certain Claims, filed March 5, 1999;
76. Ethicon's Opposition To ArthroCare's Motion For Partial Summary Judgment That Defendants Cannot Prevail On Their Enablement And Written Description Defenses As To Certain Claims, filed March 18, 1999;
77. ArthroCare's Reply Brief In Support Of ArthroCare's Motion For Partial Summary Judgment That Defendants Cannot Prevail On Their Enablement And Written Description Defenses As To Certain Claims, filed March 25, 1999;
78. Defendants' Trial Brief On The Issues Of Unenforceability And Invalidity Under 35 U.S.C. §§102, 103, and 112, filed March 29, 1999;
79. Plaintiff ArthroCare's Trial Brief Re: Validity and Enforceability Of The Patents-In-Suit, filed April 7, 1999;
80. Defendants' Notice Of Prior Art Pursuant To 35 U.S.C. §282, filed April 9, 1999;
81. April 26, 1999 Letter From Defendants To The Court Regarding Additional Claim Construction Issues;
82. Joint Proposed Jury Instructions For Claims 46, 55, 58, 59, 61, and 62 of U.S. Patent No. 5,697,536;

83. April 30, 1999 Letter From ArthroCare To The Court Regarding Additional Claim Construction Issues;

84. Expedited Motion Of Plaintiff ArthroCare Corporation Regarding Joint Jury Instructions, filed May 13, 1999;

In addition to the above-listed materials, there are numerous other papers that were filed with the Court in connection with the *Ethicon* litigation. Furthermore, depositions were taken of numerous witnesses regarding validity and enforceability issues. If the Examiner desires, Owner will submit any or all of the listed material, the other papers filed with the court, and/or transcripts of depositions to the Examiner for consideration. Owner will also provide any additional information that the Examiner desires about the *Ethicon* litigation or the materials described herein.

In addition to the *Ethicon* litigation, on July 25, 2001, Owner commenced an action in the District of Delaware against Smith & Nephew, Inc. ("Smith & Nephew") for infringement of U.S. Patent Nos. 5,697,536 ("the '536 Patent"), 5,697,882 ("the '882 Patent") and 6,224,592 ("the '592 Patent"). That action was assigned Civil Action No. 01-504-SLR. In response, Smith & Nephew filed a mirror image declaratory judgment action in the Northern District of California against Owner on August 31, 2001. The California action was assigned Case No. CV-01-03331 BZ to Magistrate Judge Zimmerman, but was later reassigned Case No. CV-01-03331 MHP to District Court Judge Patel (the Delaware and California cases collectively are referred to herein as the "*Smith & Nephew* litigation"). In these actions, Smith & Nephew asserts that the '536 Patent, the '882 Patent and the '592 Patent are invalid and not infringed. In addition, Smith & Nephew contends that the '592 Patent is unenforceable for inequitable conduct. Specifically, Smith & Nephew argues that during prosecution of the '592 patent, Owner and its attorneys should have but did not explicitly point out to the Examiner a ruling in the Court's denial of a preliminary injunction motion (*see* the document listed as Item No. 40 above) from the *Ethicon* litigation that the so-called Roos '198 patent (U.S. Patent No. 4,116, 198) disclosed the use of conductive fluid. Smith & Nephew further argues that the Court's finding in denying the preliminary injunction motion was inconsistent with a position taken by Owner during prosecution of the '592 patent, namely, that the Roos '198 patent does not disclose conductive fluid. Smith & Nephew's inequitable conduct allegations are set forth or referred to in Item Nos. 86, 88, 89, 90, 91 and 92 below.

The *Smith & Nephew* litigation is still pending before the District of Delaware. However, Smith & Nephew has agreed to dismiss the California litigation. Below is a list of materials from the *Smith & Nephew* litigation which include Smith & Nephew's primary arguments relating to validity and enforceability:

85. ArthroCare's Complaint For Patent Infringement Of U.S. Patent Nos. 5,697,536, 5,697,882 and 6,224,592 (including exhibits A--C), filed July 25, 2001;
86. Answer and Counterclaims of Smith & Nephew, filed September 13, 2001;
87. Plaintiff's ArthroCare Corporation's Motion to Enjoin Second-Filed, Duplicative Litigation; Plaintiff's Opening Brief in Support of its Motion to Enjoin Second-Filed, Duplicative Litigation (including exhibits A--F), filed September 10, 2001;
88. Defendant's Answer To Plaintiff's Opening Brief In Support Of Its Motion To Enjoin Second Filed Action (including exhibits A--C), filed September 24, 2001;
89. Motion Of Defendant Smith & Nephew, Inc. To Transfer Venue Pursuant To 28 U.S.C. §1404(a) (including exhibits A--B), September 13, 2001;
90. Smith & Nephew's Complaint For Declaratory Judgment Of Patent Invalidity, Unenforceability And Non-Infringement (including exhibits A--C), filed August 31, 2001;
91. Smith & Nephew's Notice Of Related Case (including exhibits A--E), filed August 31, 2001;
92. Smith & Nephew's Notice Of Pendency Of Other Action Pursuant To Civil Local Rule 3-13 (including exhibit A), filed August 31, 2001.
93. ArthroCare's Statement In Opposition To Smith & Nephew's Notice Of Related Case (including exhibits A--B), filed September 14, 2001;
94. ArthroCare's Statement In Opposition To Notice Of Pendency Of Other Action (including exhibits A--C), filed September 14, 2001.

Finally, the following is a list of co-pending applications relating to the technology covered by the '536 Patent:

Application No.	Filing Date
08/761,096	05-Dec-1996
09/026,852	20-Feb-1998
09/041,934	13-Mar-1998
09/258,516	26-Feb-1999
09/539,147	30-Mar-2000
09/709,035	08-Nov-2000
09/758,403	10-Jan-2001
09/766,168	19-Jan-2001
09/836,940	17-Apr-2001
09/134,542	13-Aug-1998
09/262,281	04-Mar-1999
09/314,247	18-May-1999
09/438,592	12-Nov-1999
09/484,087	18-Jan-2000
09/504,530	15-Feb-2000
09/273,612	22-Mar-1999
09/360,075	23-Jul-1999
09/197,013	20-Nov-1998
09/629,251	27-Jul-2000
09/372,454	11-Aug-1999
09/845,034	27-Apr-2001
09/570,394	12-May-2000
09/501,327	09-Feb-2000
09/771,299	25-Jan-2001
09/054,660	03-Apr-1998
09/338,842	23-Jun-1999
09/347,390	06-Jul-1999
09/062,869	20-Apr-1998
09/735,426	12-Dec-2000
09/354,835	16-Jul-1999
09/507,366	18-Feb-2000
09/109,219	30-Jun-1998
09/477,832	05-Jan-2000
60/299,094	18-Jun-2001
09/357,774	21-Jul-1999
09/032,375	27-Feb-1998
09/457,201	06-Dec-1999
09/586,295	02-Jun-2000
09/314,611	19-May-1999
09/361,674	27-Jul-1999
09/791,504	22-Feb-2001
09/293,231	16-Apr-1999
09/313,956	18-May-1999
09/718,160	20-Nov-2000
09/313,957	18-May-1999
60/276,863	16-Mar-2001
09/464,884	16-Dec-1999

Application No.	Filing Date
09/162,110	28-Sep-1998
09/562,650	01-May-2000
09/774,448	30-Jan-2001
09/482,141	12-Jan-2000
09/480,880	10-Jan-2000
09/074,020	06-May-1998
09/562,496	01-May-2000
09/603,833	26-Jun-2000
09/776,799	05-Feb-2001
09/839,427	20-Apr-2001
09/780,745	09-Feb-2001
60/304,297	09-Jul-2001
09/571,343	16-May-2000
09/412,103	04-Oct-1999
09/860,662	18-May-2001
09/026,698	20-Feb-1998
09/512,742	24-Feb-2000
09/478,729	06-Jan-2000
09/848,843	03-May-2001
09/665,441	19-Sep-2000
09/765,832	19-Jan-2001
09/708,962	08-Nov-2000
09/689,264	11-Oct-2000
09/676,194	28-Sep-2000
09/747,311	20-Dec-2000
09/679,394	03-Oct-2000
60/299,082	18-Jun-2001
60/299,095	18-Jun-2001
09/796,094	28-Feb-2001

Respectfully submitted,

John T. Raffle
Reg. No. 38,585

ArthroCare Corporation
595 N. Pastoria Avenue
Sunnyvale, CA 94086
(408) 736-0224

FORM PTO-1449 (Modified) LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)	Attorney Docket No. 16238-000610	Patent No.: *5,697,536*
	Applicant: PHILIP E. EGGERS et al.	
	Issue Date: *December 16, 1997*	Group:

Reference Designation — **U.S. PATENT DOCUMENTS**

Examiner Initial	Document No.	Date	Name	Class	Sub-class	Filing Date
___ AA	4,682,596	07/28,1987	Bales et al.	128	303	
___ AB	5,514,130	05/07/96	Baker	606	41	
___ AC	5,078,717	01/07/92	Parins et al.	606	48	
___ AD	5,697,281	12/16/97	Eggers et al.	604	114	
___ AE	5,697,882	12/16/97	Eggers et al.	604	114	
___ AF	5,697,909	12/16/97	Eggers et al.	604	114	
___ AG	5,725,524	03/10/98	Mulier et al.	606	41	
___ AH	5,609,151	03/11/97	Mulier et al.	128	642	
___ AI	4,043,342	08/23/97	Morrison, Jr.	128	303	
___ AJ	4,184,492	01/22/80	Meinke et al.	128	303	
___ AK	4,248,231	02/03/81	Herczog et al.	128	303	

FOREIGN PATENT DOCUMENTS

	Document No.	Date	Country	Class	Sub-class	Translation (yes/no)
___ AL	97/00647	01/09/97	WIPO	A61B	17/39	
___ AM	97/00646	01/09/97	WIPO	A61B	17/39	
___ AN	EP 0 703 461	03/27/96	Europe	G01R	27/02	
___ AO	EP 0 754 437	01/22/97	Europe	A61B	17/39	
___ AP	93/20747	10/28/93	WIPO	A61B	5/00	
___ AQ	97/48345	12/24/97	WIPO	A61B	17/39	
___ AR	98/27880	07/02/98	WIPO	A61B	17/39	

OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

___ AS	Pearce, John A. (1986) *Electrosurgery*, pgs. 17, 69-75, 87, John Wiley & Sons, New York.
___ AS1	V.E. Elsasser et al. *Acta Medicotechnica* Vol. 24, No. 4, pp. 129-134 (1976).
___	

EXAMINER — DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449 (Modified) LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)	Attorney Docket No. 16238-000610	Patent No.: *5,697,536*
	Applicant: PHILIP E. EGGERS et al.	
	Issue Date: *December 16, 1997*	Group:

Reference Designation — **U.S. PATENT DOCUMENTS**

Examiner Initial	Document No.	Date	Name	Class	Sub-class	Filing Date
___ AT	4,706,667	11/17/87	Roos	128	303	
___ AU	5,584,872	12/17/96	LaFontaine et al.	607	117	
___ AV	5,676,693	10/14/97	LaFontaine et al.	607	116	
___ AW	5,370,675	12/06/94	Edwards et al.	607	101	
___ AX	5,080,660	01/14/92	Buelna	606	45	
___ AY	5,417,687	05/23/95	Nardella et al.	606	32	
___ AZ	4,232,676	11/11/80	Herczog	128	303	
___ BA	4,033,351	07/05/77	Hetzel	128	303	
___ BB	5,112,330	05/12/92	Nishigaki et al.	606	46	
___ BC	5,843,019	12/01/98	Eggers et al.	604	22	
___ BD	5,871,469	02/16/99	Eggers et al.	604	114	
___ BE	5,007,908	04/16/91	Rydell	606	47	

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	Document No.	Date	Country	Class	Sub-class	Translation (yes/no)
___ BF	2 327 350	01/27/99	UK	A61B	17/39	
___ BG	2 327 351	01/27/99	UK	A61B	17/39	
___ BH	2 327 352	01/27/99	UK	A61B	17/39	
___ BI	WO95/34259	12/21/95	WIPO	A61F	5/48	
___ BJ	57-57802	04/05/82	JP	A61B	1/00	

OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

___ BK	Buchelt, M. et al. "Excimer Laser Ablation of Fibrocartilage: An In Vitro and In Vivo Study," (1991) LASERS IN SURGERY AND MEDICINE 11:271-279.
___ BL	Costello, A. J. et al. "Nd:YAG Laser Ablation of the Prostate as a Treatment of Benign Prostatic Hypertrophy," (1992) LASERS IN SURGER AND MEDICINE 12:121-124.

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	Applicant: PHILIP E. EGGERS et al.	
	Issue Date: *December 16, 1997*	Group: 3739

Reference Designation — **U.S. PATENT DOCUMENTS**

Examiner Initial	Document No.	Date	Name	Class	Sub-class	Filing Date
___ BM	5,192,280	03/09/93	Parins	606	48	
___ BN	5,662,680	09/02/97	Desai	606	210	
___ BO	5,249,585	10/05/93	Turner et al.	607	99	
___ BP	5,190,517	03/02/93	Zieve et al.	604	22	
___ BQ	5,366,443	11/22/94	Eggers et al.	604	114	
___ BR	5,122,138	06/16/92	Manwaring	606	46	
___ BS	5,330,470	07/19/94	Hagen	606	42	
___ BT	5,647,869	07/15/97	Goble et al.	606	37	
___ BU	4,040,426	08/09/77	Morrison, Jr.	128	303	
___ BV	4,548,207	10/22/85	Reimels	128	303	
___ BW	4,823,791	04/25/89	D'Amelio et al.	123	303	
___ BX	5,098,431	03/24/92	Rydell	606	48	
___ BY						

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	Document No.	Date	Country	Class	Sub-class	Translation (yes/no)
___ BZ	WO 94/04220	03.03.94	WIPO	yes	A61N	1/06
___ CA	97/24073	07/10/97	WIPO	A61B	17/39	
___ CB	97/24993	07/17/97	WIPO	A61B	17/39	
___ CC	97/24994	07/17/97	WIPO	A61B	17/39	
___ CD	97/48346	12/24/97	WIPO	A61B	17/39	
___ CE	96/00042	01/04/96	WIPO	A61B	17/39	

OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

___ CF	J.W. Ramsey et al. *Urological Research* Vol. 13, pp. 99-102 (1985).
___ CG	Slager et al. *JACC* 5(6):1382-6 (1985).
___	

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	Issue Date: *December 16, 1997*	Group: 3739

Reference Designation — **U.S. PATENT DOCUMENTS**

Examiner Initial	Document No.	Date	Name	Class	Sub-class	Filing Date
___ CH	5,217,457	06/08/93	Delahuerga et al.	606	42	
___ CI	4,240,441	12/23/80	Khalil	128	692	
___ CJ	5,197,963	03/30/93	Parins	606	46	
___ CK	5,944,715	08/31/99	Goble et al.	606	41	
___ CL	5,057,106	10/15/91	Kasevich et al.	606	33	
___ CM	4,860,752	08/29/89	Turner	128	422	
___ CN	5,807,395	09/15/98	Mulier et al.	606	41	
___ CO	5,700,262	12/23/97	Acosta et al.	606	48	
___ CP	5,441,499	08/15/95	Fritzsch	606	45	
___ CQ	5,035,696	07/30/91	Rydell	606	47	
___ CR	5,749,869	05/12/98	Lindenmeier et al.	606	34	
___ CS	5,267,997	12/07/93	Farin et al.	606	38	
___ CT	5,281,218	01/25/94	Imran	606	41	
___ CU	5,125,928	06/30/92	Parins et al.	606	48	
___ CV	5,496,312	03/05/96	Klicek	606	34	

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	Document No.	Date	Country	Class	Sub-class	Translation (yes/no)
___ CW	98/07468	02/26/98	WIPO	A61N	1/40	
___ CX	2 308 981	07/16/97	GB	A61B	17/36	
___ CY	2 308 980	07/16/97	GB	A61B	17/36	
___ CZ	2 308 979	07/16/97	GB	A61B	17/36	

OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

___ DA	R. Tucker et al., Abstract P14-11, p. 248, "A Bipolar Electrosurgical Turp Loop"
___ DB	R. Tucker et al. *J. of Urology* Vol. 141, pp. 662-665, (1989).
___ DC	R. Tucker et al. *Urological Research* Vol. 18, pp. 291-294 (1990).

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	Applicant: PHILIP E. EGGERS et al.	
	Issue Date: *December 16, 1997*	Group: 3739

Reference Designation — **U.S. PATENT DOCUMENTS**

Examiner Initial	Document No.	Date	Name	Class	Sub-class	Filing Date
___ DD	5,810,809	09/22/98	Rydell	606	49	
___ DE	5,800,431	09/01/98	Brown	606	42	
___ DF	5,885,277	03/23/99	Korth	606	35	
___ DG	6,068,628	05/30/00	Fanton et al.	606	41	
___ DH	6,238,391	05/29/01	Olsen et al.	606	41	
___ DI	6,254,600	07/03/01	Willink et al.	606	41	
___ DJ	6,264,652	07/24/01	Eggers et al.	606	41	
___ DK	6,013,076	01/11/00	Goble et al.	606	41	
___ DL	6,015,406	01/18/00	Goble et al.	606	41	
___ DM	6,027,501	02/22/00	Goble et al.	606	41	
___ DN	6,004,319	12/21/99	Goble et al.	606	48	
___ DO	6,039,734	03/21/00	Goble et al.	606	41	
___ DP	6,056,746	05/02/00	Goble et al.	606	48	
___ DQ	6,093,186	07/25/00	Goble et al.	606	34	
___ DR	6,074,386	06/13/00	Goble et al.	606	34	
___ DS	6,090,106	07/18/00	Goble et al.	606	41	

FOREIGN PATENT DOCUMENTS

	Document No.	Date	Country	Class	Sub-class	Translation (yes/no)
___ DT	98/27879	07/02/98	WIPO	A61B	17/36	
___ DU	57-117843	07/22/82	JP	A61B	17/39	
___ DV	99/51158	10/14/99	WIPO	A61B	17/39	

OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

___ DW	Kramolowsky et al. *J. of Urology* Vol. 143, pp. 275-277 (1990).
___ DX	Kramolowsky et al. *J. of Urology* Vol. 146, pp. 669-674 (1991).
___ DY	Slager et al. *Z. Kardiol.* 76:Suppl. 6, 67-71 (1987).

EXAMINER — DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449 (Modified) LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)	Attorney Docket No. 16238-000610	Patent No.: *5,697,536*
	Applicant: PHILIP E. EGGERS et al.	
	Issue Date: *December 16, 1997*	Group: 3739

Reference Designation — **U.S. PATENT DOCUMENTS**

Examiner Initial	Document No.	Date	Name	Class	Sub-class	Filing Date
___ DZ	5,681,282	10/28/97	Eggers et al.	604	114	
___ EA						
___ EB	5,766,153	06/16/98	Eggers et al.	604	114	
___ EC	5,810,764	09/22/98	Eggers et al.	604	23	
___ ED	5,683,366	11/04/97	Eggers et al.	604	114	
___ EE	4,727,874	03/01/88	Bowers et al.	128	303	
___ EF	5,318,563	06/07/94	Malis et al.	606	38	
___ EG	5,556,397	09/17/96	Long et al.	606	48	
___ EH	5,897,553	04/27/99	Mulier	606	41	
___ EI	5,888,198	03/30/99	Eggers et al.			
___ EJ	5,891,095	04/06/99	Eggers et al.			
___ EK	5,902,272	05/11/99	Eggers et al.			
___ EL						
___ EM						
___ EN						
___ EO	6,224,592	05/01/01	Eggers et al.	606	32	

FOREIGN PATENT DOCUMENTS

	Document No.	Date	Country	Class	Sub-class	Translation (yes/no)
___ EP	99/51155	10/14/99	WIPO	A61B	17/36	
___ EQ						
___						

OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

___	
___	

EXAMINER — DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

CERTIFICATE OF SERVICE

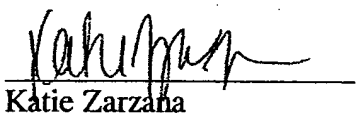
I hereby certify that on this 12th day of October, 2001, a true and correct copy of the document listed below was caused to be served on the attorneys of record at the following addresses as indicated:

1. Information Disclosure Statement and Form PTO-1449

BY U.S. POSTAL SERVICE
FIRST CLASS MAIL

William C. Fuess
FUESS & DAVIDENAS
10951 Sorrento Valley Road, Suite II-G
San Diego, CA 92121-1613

Executed on October 12, 2001 at Sunnyvale, California.



Katie Zarzana

UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, D.C. 20231
www.uspto.gov

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
90/005,601	12/30/1999		

OC000000005491832

JOHN T. RAFFLE
ARTHROCARE CORPORATION
595 N. PASTORIA AVE.
SUNNYVALE, CA 94085-2936

Date Mailed: 10/20/2000

NOTICE REGARDING POWER OF ATTORNEY

This is in response to the Power of Attorney filed 09/18/2000.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.

Customer Service Center
Initial Patent Examination Division (703) 308-1202
ATTORNEY/APPLICANT COPY

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

CONTROL NUMBER	FILING DATE	PATENT UNDER REEXAMINATION	ATTORNEY DOCKET NO.
90/005,601	12/30/99	5697536	

QM31/1027

JOHN T. RAFFLE
ARTHROCARE CORPORATION
595 N. PASTORIA AVE.
SUNNYVALE CA 94085-2936

EXAMINER	
MENDEZ, M	
ART UNIT	PAPER NUMBER
3763	

DATE MAILED: 10/27/00

ORDER GRANTING/DENYING REQUEST FOR REEXAMINATION

The request for reexamination has been considered. Identification of the claims, the references relied on, and the rationale supporting the determination are attached.

Attachment(s): ☐ PTO-892, ☒ PTO-1449, ☐ Other: _____.

1. ☒ The request for reexamination is GRANTED.

RESPONSE TIMES ARE SET TO EXPIRE AS FOLLOWS:

For Patent Owner's Statement (optional): TWO MONTHS from the mailing date hereof. 37 CFR 1.530(b). **EXTENSIONS OF TIME ARE GOVERNED BY 37 CFR 1.550(c).**

For Requester's reply (optional): TWO MONTHS from the date of service of any patent owner's statement. 37 CFR 1.535. **NO EXTENSION OF TIME IS PERMITTED.** If patent owner does not file a timely statement under 37 C.F.R. 1.530(b), no reply by requester is permitted.

2. ☐ The request for reexamination is DENIED.

This decision is not appealable. 35 U.S.C. 303(c). Requester may seek review by petition to the Commissioner within ONE MONTH from the mailing date hereof. 37 CFR 1.515(c). **EXTENSIONS OF TIME ONLY UNDER 37 CFR 1.183.**

In due course, a refund under 37 CFR 1.26(c) will be made to requester (listed below if not patent owner) ☐ by Treasury check, ☐ by credit to Deposit Account No. _____ unless notified otherwise. 35 U.S.C. 303(c).

(Third party requester's correspondence address)

Reexam Control No.: 90/005,601
Art Unit 3763

A substantial new question of patentability affecting at least claims 1-3, 14, 16, 22, 27, 30, 33, 38, 41-48, 55, 57, 60 and 63 of U.S. Patent No. 5,697,536 to Eggers et al. is raised by the request.

The request indicates that the requester considers at least claims 1-3, 14, 16, 22, 27, 30, 33, 38, 41-48, 55, 57, 60 and 63 of Eggers et al. as being anticipated by U.S. Patent No. 4,116,198 to Roos under 35 U.S.C. 102.

It is agreed that a reasonable examiner would consider U.S. Patent No. 4,116,198 to Roos to be important prior art which would clearly be material in the examination of the claims as pointed out in detail in the request.

The reference is therefore considered to raise a substantial question of patentability.

Accordingly, reexamination of all the patent claims is deemed proper.

Manuel Antonio Mendez
January 25, 2000

WYNN WOOD COGGINS
SUPERVISORY PATENT EXAMINER

FORM PTO-1449

DEC 10 1999 PATENT & TRADEMARK OFFICE

Atty. Docket No.:	Patent No.:
	5,697,536

LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT

Inventor(s):	
Eggers et al.	
Issue Date	Group Art:
12/16/97	unknown

U.S. PATENT DOCUMENTS

Examiner Initial		Document No.	Date	Name	Class	Sub Class	Filing Date If Appropriate
	AA	4,116,198	09/26/78	Roos	128	303.15	05/14/76
	AB						
	AC						
	AD						
	AE						
	AF						
	AG						
	AH						
	AI						
	AJ						
	AK						

FOREIGN PATENT DOCUMENTS

		Document No.	Date	Country	Class	Sub Class	Translation Yes	Translation No
	AL							
	AM							
	AN							

OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	AO	
	AP	
	AQ	

EXAMINER: _____ DATE CONSIDERED: January 20, 00

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FUESS & DAVIDENAS
ATTORNEYS AT LAW

10951 SORRENTO VALLEY ROAD
SUITE II-G
SAN DIEGO, CALIFORNIA 92121-1613

INTELLECTUAL PROPERTY LAW

(858) 452-8293, 1478
FACSIMILE *(858) 452-6035*
E-MAIL *fuess@funtv.com*

WILLIAM C. FUESS
JOSEPH A. DAVIDENAS
ROBERT F. HANSEN
MARK J. HARTENSTEIN†
† ADMITTED IN IDAHO

OF COUNSEL

DONALD W. CANADY
JAMES H. MEADOWS

EAST COUNTY OFFICE
17258 AMARILLO ROAD
RAMONA, CALIFORNIA 92065
(760) 788-7401
FACSIMILE *(760) 788-7401*

December 23, 1999

Hira V. Thapliyal
Arthrocare Corporation
595 North Pastoria Avenue
Sunnyvale, CA 94086

RE: Our Ref. No. EGG 0001V
Transmission of REEXAMINATION REQUEST

Dear Sir/Madame:

Enclosed is a copy of a REEXAMINATION REQUEST sent to the PTO this day on U.S. Patent No. 5,697,536 to Eggers, et al. assigned to Arthrocare Corporation

Sincerely,

William C. Fuess

William C. Fuess

WCF/sel
Enclosures

P A T E N T

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent No. : 5,697,536

Date of Issue : December 16, 1997

Name of Patentee : Eggers et al.

Title of Invention : SYSTEM AND METHOD FOR ELECTROSURGICAL CUTTING AND ABLATION

Prior Examiner: Manuel Mendez

REEXAMINATION REQUEST

Commissioner of Patents
and Trademarks
Box REEXAM
Washington, D.C. 20231

CERTIFICATE UNDER 37 CFR 1.8: The Undersigned hereby certifies that this paper or papers, as described herein below, are being deposited with the United States Postal Service, on the date shown below with sufficient postage as first class mail in an envelope addressed to the:
Commissioner of Patents and Trademarks
Box REEXAM
Washington, D.C. 20231
On this 23rd day of December, 1999.

By: William C. Fuess
William C. Fuess
Reg. No. 30,054

Dear Sir:

Reexamination is requested pursuant to 35 U.S.C. §§302-307 and 37 CFR §1.510 of the above-identified patent. The following items are enclosed.

1. Prior art relied upon and a Form PTO-1449 (37 CFR §1.510 (b)(3)).

2. A substantial new question of patentability raised by the above prior art and the pertinency of the cited prior art of the claims for which reexamination is requested is set forth in the attached STATEMENT OF NEW QUESTION OF PATENTABILITY (37 CFR §§1.510 (b)(1) and (2)).

3. A cut-up copy of the original patent showing single columns of the patent reproduced on one side of a separate paper (37 CFR §1.510 (b) (4)).

4. The signature below certified that:

A copy of this request and all accompanying papers has been served on the patent owner at the address provided for in 37 CFR §1.33(c) by depositing the documents in an

envelope bearing first class postage in an official U.S. Postal Service repository at the date set forth below addressed as follows:

Name Hira V. Thapliyal
Arthrocare Corporation

Address 595 North Pastoria Avenue

Sunnyvale, California 94086

5. A check in the amount of $2,520.00 is attached. (37 CFR §§1.20(c) and 1.510(a)).

Please charge any deficiency to Deposit Account No._____.

Any refund should be made by check.

The name and address of the person making this request is:

Name William C. Fuess
Reg. No. 30,054

Address FUESS & DAVIDENAS
10951 Sorrento Valley Road
Suite II-G
San Diego, CA 92121-1613

Tel. No.: (858) 452-9293
Facsimile No. (858) 452-6035
E-mail: fuess@funtv.com

Please address all future correspondence as follows:

William C. Fuess
FUESS & DAVIDENAS
10951 Sorrento Valley Road
Suite II-G
San Diego, CA 92121-1613

Respectfully submitted,

Dated: 12/23/99
December 23, 1999

William C. Fuess
Reg. No. 30,054

STATEMENT OF NEW QUESTION OF PATENTABILITY

I. Patent and Claims for which Reexamination is Requested

Reexamination under 35 U.S.C. §§302-307 and 37 CFR §1.510 is requested of U.S. Patent No. 5,697,536 which issued on December 16, 1997 to Eggers et al., and is assigned to Arthrocare Corporation (hereinafter "the Eggers '536 Patent"). Reexamination is requested of claims 1-3, 14, 16, 22, 27, 30, 33, 38, 41-48, 55, 57, 60 & 63, in view of U.S. Patent No. 4,116,198 to Roos (hereinafter "the Roos '198 Patent"). It is noted that the Roos '198 Patent was not before the Examiner during the prosecution of the Eggers '536 Patent.

II. Statement of Substantial New Question of Patentability

A. Overview

The Eggers '536 Patent is directed to devices employing high frequency voltage to cut and ablate tissue. (Eggers '536 1:19-21).

The Eggers '536 Patent discloses and claims electrosurgical devices that are designed and intended to be used in conductive fluids such as isotonic saline. The electrosurgical device generally includes a current supplying radio frequency generator; an active electrode, or an electrode terminal, mounted near the tip of a surgical probe; a return electrode positioned rearward of and in a spaced apart condition from said active electrode; an insulator separating the active and return electrodes; and, an

electrically conducting fluid path in electrical contact with the active and return electrodes.

B. Subject Matter of Claims 1-3, 14, 16, 22, 27, 30, 33, 38, 41-48, 55, 57, 60 & 63

The independent claims are claims 1, 45 and 63.

Each of the independent claims is directed to an "electrosurgical system." The statement of intended purpose in the preamble of claim 1 is one of "use," namely "for use with a high frequency power supply and an electrically conducting fluid supply" (Id., 15:6-7), whereas the statement of intended purpose in both claims 45 and 63 include the following functional language: "for applying electrical energy to a target site on a structure within or on a patient's body" (Id., 18:13-15, 20:8-10)[1]. With respect to the preambles, it is further noted that

---

[1]Reexam requestor respectfully asserts that the preamble language of claims 1, 45 and 63 is **not** limiting. The Court of Customs and Patent Appeals, predecessor to the Court of Appeals for the Federal Circuit, in Kropa v. Robie, 187 F.2d 150, 88 USPQ 478 (CCPA 1951) reviewed 37 of its own prior decisions, 27 of which held that the preamble was not a limitation. The CCPA distilled the following synthesis from the cases:

> [T]he preamble has been denied the effect of a limitation where the claim or count was drawn to a structure and the portion of the claim following the preamble was a self-contained description of the structure not depending for completeness upon the introductory clause; or where the claim or count was drawn to a product and the introductory clause merely recited a property inherent in the old composition defined by the remaining part of the claim. In those cases, the claim or count apart from the introductory clause completely defined the subject matter, and the preamble merely stated a purpose or intended use of that subject matter.

(Id. at 152).

The CAFC provide a noteworthy analysis in C.R. Bard Inc. v. M3 Systems Inc. 48 USPQ 1225, 1230 (Fed.Cir. 1998), one directly applicable to claim 1 of the Eggers '536 Patent, wherein the preamble of claim 21 of the Bard '056

those of claims 45 and 63 are identical.

The recited elements of the claim 1 "system" for use with a high frequency power supply and an electrically conducting fluid supply include an electrosurgical probe, a return electrode, and a fluid delivery element. The probe comprises a shaft having proximal and distal ends, an electrode terminal disposed near the distal end of the shaft, and a connector near the proximal end of the shaft. The connector electrically couples the electrode terminal to the electrosurgical power supply, whereas the return

---

patent reads as follows:

> 21. A biopsy needle for use with a tissue sampling device having a housing with a forward end, a first slide mounted for longitudinal motion within said housing, and a second slide mounted for longitudinal motion within said housing, said biopsy needle comprising:

Id. at 1229. The Court noted that:

> M3 Systems has incorrectly construed the claim preamble. A preamble may serve a variety of purposes, depending on its content. It may limit the scope of the claim, for example when patentability depends on limitations stated in the preamble, as in In re Stencel, 828 F.2d 751, 754, 4 USPQ2d 1071, 1073 (Fed.Cir. 1987), or when the pramble contributes to the definition of the claimed invention, as in Bell Communications Research, Inc. v. Vitalink Communications Corp., 55 F.3d 615, 620, 34 USPQ2d 1816, 1820 (Fed.Cir. 1995). **In this case, however, the preamble simply states the intended use or purpose of the invention,** as in Loctite Corp. v. Ultraseal Ltd., 781 F.2d 861, 868, 228 USPQ 90, 94 (Fed. Cir. 1985). Such a preamble usually does not limit the scope of the claims unless the preamble provides antecedents for ensuing claim terms and limits the claim accordingly. In Vaupel Textilmaschinen KG v. Meccanica Euro Italia S.P.A., 944 F.2d 870, 880, 20 USPQ2d 1045, 1053 (Fed.Cir. 1991), for example, the preamble described a "reference point" that provided guidance in understanding and construing the claim.
>
> In the case at bar, the preamble of claim 21 recites the portion and structure of the gun housing into which the needle fit, and provides reference points in the gun that aid in defining the needles as set forth in the body of the claim. M3 Systems is incorrect in stating that the preamble must contain details of the integrated mechanical cocking structure, for the gun structure is not part of the separate claims to the needles. The question of anticipation of the '056 claims relates to the needles, not the gun.

electrode is adapted for said purpose. The fluid delivery element defines a fluid path which is in electrical contact with the return electrode and the electrode terminal. The fluid path has an inlet adapted to be fluidly coupled to the fluid supply for directing fluid along the fluid path to generate a current flow path between the return electrode and electrode terminal (i.e., conductively link the passive and active electrodes using a conductive fluid).

The recited elements of the claim 45 "system" for applying electrical energy include a high frequency power supply, an electrosurgical probe, a return electrode, and an electrically conducting fluid supply for directing fluid so as to generate a current flow path between the return electrode and the electrode terminal. In contradistinction to claim 1, claim 45 positively recites the power and fluid supplies in the body of the claim as opposed to in the preamble as noted hereinabove. Both the probe and the return electrode are as recited in claim 1, with the functional terms "for" and "adapted to" eliminated, as the power supply is positively recited in claim 45.

The first eleven (11) lines of claim 63 read verbatim as claim 45. Thereafter, claim 63, as claim 45, requires an electrically conducting fluid supply, however claim 63 further requires a fluid delivery element. The fluid delivery element defines a fluid path electrically coupled to the electrode terminal for directing electrically conductive fluid to a target

site and the electrode terminal.

Claims 2, 3, 14, 16, 22, 27, 30, 33, 38, and 41-44 of the Eggers '536 Patent, directly or indirectly depend from claim 1. Each will be taken up seriatim.

Claim 2 of the Eggers '536 Patent depends from claim 1, and requires that the passive or return electrode form a portion of the shaft of the probe.

Claim 3 of the Eggers '536 Patent depends from claim 2, and requires that the "electrosurgical system" further include an insulating member circumscribing the passive electrode, the passive electrode being spaced from the electrode terminal so to minimize direct contact between the passive electrode and a body structure when the electrode terminal is positioned for electrosurgery.

Claim 14 of the Eggers '536 Patent depends from claim 1, and requires that the electrode terminal comprise a single active electrode disposed near the distal end of the probe shaft.

Claim 16 of the Eggers '536 Patent depends from claim 1, and requires that the "electrosurgical system" further include a current limiting element for controlling current flow through the electrode terminal to inhibit power dissipation into the medium surrounding the target site.

Claim 22 of the Eggers '536 Patent depends from claim 16, and requires that the current limiting element be a passive current limiting element selected from the group consisting

essentially of inductors, capacitors, resistors and combinations thereof.

Claim 27 of the Eggers '536 Patent depends from claim 1, and requires that the "electrosurgical system" further include means for controlling power to the electrode terminal based on the electrical impedance between the electrode terminal and the return electrode.

Claim 30 of the Eggers '536 Patent depends from claim 1, and requires that the electrode terminal and the return electrode be configured to affect the electrical break down of tissue in the immediate vicinity of the electrode terminal when high frequency voltage is applied between the electrode terminal and the return electrode in the presence of electrically conducting fluid.

Claim 33 of the Eggers '536 Patent depends from claim 1, and requires that the electrode terminal have a distal portion configured for generating high electric field intensities sufficient to cause molecular disintegration of a body structure at the target site.

Claim 38 of the Eggers '536 Patent depends from claim 1, and requires that the electrode terminal be configured for the cutting of tissue.

Claim 41 of the Eggers '536 Patent depends from claim 1, and requires that the electrode terminal and the return electrode be configured to affect the ablation of tissue adjacent the electrode terminal, upon the application of sufficient voltage

therebetween, such that a portion of such tissue is volumetrically removed.

Claim 42 of the Eggers '536 Patent depends from claim 1, and requires that the electrode terminal be disposed at the distal tip of the electrosurgical probe.

Claims 46-48, 55, 57, & 60 of the Eggers '536 Patent, directly or indirectly depend from claim 45. Each will be taken up *seriatim*.

Claim 43 of the Eggers '536 Patent depends from claim 42, and requires that the return electrode be disposed proximally of the electrode terminal on the electrosurgical probe.

Claim 44 of the Eggers '536 Patent depends from claim 1, and requires that the electrode terminal be flexible, be disposed at the distal tip of the probe, and be extendable relative thereto.

Claims 46 and 47 of the Eggers '536 Patent each depend from claim 45 and recite limitations identical to or similar to those of claims 2 & 3 respectively.

Claim 48 of the Eggers '536 Patent depends from claim 45, and requires that the return electrode be an inner tubular member defining an axial lumen within the return electrode, the axial lumen having an inlet in communication with the electrically conducting fluid supply and an outlet in fluid communication with the electrode terminal.

Claims 55, 57 and 60 of the Eggers '536 Patent each depend

from claim 45 and recite limitations identical to or similar to those of claims 42, 16 & 27 respectively.

C. Basis for Substantial New Question of Patentability

It is submitted that claims 1-3, 14, 16, 22, 27, 30, 33, 38, 41-48, 55, 57, 60 & 63 of the Eggers '536 Patent are anticipated by the Roos '198 Patent under 35 U.S.C. §102(b), and should be rejected.

The Roos '198 Patent discloses a bipolar radio frequency electrosurgical probe for removing tissue. The device includes active and return electrodes at the distal end of a probe shaft (endoscope) coupled to a radio frequency generator by connectors at the proximal end. Inductors, capacitors and resistors are further disclosed by Roos for controlling the current flow through the active electrode, so as to inhibit power dissipation into the area surrounding the target site, and a variable tap is provided for controlling the power to the active electrode.

The active electrode projects from the distal end of the probe shaft to engage a target site, with the return electrode being adjacent thereto. The return electrode is spaced back from the active electrode and positioned on, within or integral to the probe shaft, such that the return electrode cannot contact tissue when the device is removing or otherwise treating tissue.

The Roos bipolar device is intended to be used in electrically conductive fluid, with the electrical current flowing between the active and return electrodes through the

fluid. A fluid delivery element defines a fluid path for fluid flow from a fluid supply when the Roos device is used as a "system," as is contemplated. The electrically conductive fluid provides a low impedance path between the active and return electrodes.

An electrically insulating member substantially surrounds the proximal portion of the active electrode, insulating the proximal portion of the electrode from the electrically conductive fluid while housing and supporting the active electrode. The small loop construction of the active electrode, which is inherently flexible and is disclosed as being extendable relative to the distal tip of the probe, provides a high current density which is known to effect sought after tissue removal.

D. Application of Prior Art References to Claims

In accordance with the requirements set forth in 35 U.S.C. §302, the cited prior art is applied to claims 1-3, 14, 16, 22, 27, 30, 33, 38, 41-48, 55, 57, 60 & 63 of the Eggers '536 Patent on an element by element basis as follows:

Claim/ Element		
Claim 1/ Element		

Claim/ Element		
A	1. An electrosurgical system for use with a high frequency power supply and an electrically conducting fluid supply, the system comprising:	Roos '198 shows a combination of elements, i.e., a system, (e.g., FIG. 4) for use with a high frequency power supply and an electrically conducting fluid supply as evidenced by the electrically conducting fluid (i.e., wash water) passage shown and disclosed by Roos (e.g., FIG. 1, reference numeral 29 and 4:51-54).
B	an electrosurgical probe comprising a shaft having a proximal end and a distal end, an electrode terminal disposed near the distal end, and a connector near the proximal end of the shaft for electrically coupling the electrode terminal to the electrosurgical power supply;	Roos '198 generally shows an electrosurgical probe (FIG. 1) comprising a shaft 13 having proximal and distal ends. An electrode terminal 12 is disposed near the distal end of shaft 13, with connectors, as schematically shown in FIGS. 4-6 & 9, near the proximal end of the shaft 13 for electrically coupling the electrode terminal 12 to the electrosurgical power supply 15.
C	a return electrode adapted to be electrically coupled to the electrosurgical power supply; and	Roos '198 shows a return electrode 11 adapted to be electrically coupled to the electrosurgical power supply 15, specifically via rigid metallic shield 14 (FIG. 1).
D	a fluid delivery element defining a fluid path in electrical contact with the return electrode and the electrode terminal, the fluid path having an inlet adapted to be fluidly coupled to the electrically conducting fluid supply for directing fluid along the fluid path to generate a current flow path between the return electrode and the electrode terminal.	Roos '198 shows a fluid delivery element (FIG. 1), namely the annular space bounded by the interior of shaft wall 13 and the exterior of the fiber optical system 17 (4:51-57), which defines fluid path 29 (FIG. 1) for fluid flow from a fluid supply, not shown but inherently present. The fluid path 29 is in electrical contact with return electrode 11 and the electrode terminal 12. The fluid path 29 inherently has an inlet adapted to be fluidly coupled to a supply of fluid for directing fluid along the fluid path 29, which by its nature will generate a current flow path between the return electrode 11 and the electrode terminal 12.

Claim/ Element		
Claim 2/ Element		
A	2. An electrosurgical system as in claim 1, wherein the return forms a portion of the shaft of the electrosurgical probe.	Roos '198 shows in FIGS. 7 & 8, a return electrode 11 that forms a portion of the shaft 13 of the electrosurgical probe.
Claim 3/ Element		
A	3. An electrosurgical system as in claim 2, further including an insulating member circumscribing the return electrode,	Roos '198 shows in FIGS. 7 & 8 insulating members 35 & 36 circumscribing return electrode 11. Note, 7:17-20.
B	the return electrode being sufficiently spaced from the electrode terminal to minimize direct contact between the return electrode and a body structure at the target site when the electrode terminal is positioned in close proximity or in partial contact with the body structure.	Roos '198 shows in FIGS. 7 & 8, a return electrode 11 sufficiently spaced from electrode terminal 12 to minimize direct contact between return electrode 11 and a body structure at the target site when electrode terminal 12 is positioned in close proximity or in partial contact with the body structure.
Claim 14/ Element		
A	14. The electrosurgical system of claim 1 wherein the electrode terminal comprises a single active electrode disposed near the distal end of the shaft.	Roos '198 shows in FIGS. 1, 2, 3 & 7, a single active electrode 12 disposed near the distal end of shaft 13.
Claim 16/ Element		
A	16. The electrosurgical system of claim 1 further comprising a current limiting element for controlling current flow through the electrode terminal to inhibit power dissipation into the medium surrounding the target site.	Roos '198 shows in FIG. 4, multiple current limiting elements (i.e., inductor 25, capacitors 26, 28 etc., and resistor "R") for controlling current flow through electrode terminal 12 to inhibit power dissipation into the medium surrounding the target site. Note, 5:26-29, 31-34, and 38-45.

Claim/ Element		
Claim 22/ Element	22. The electrosurgical system of claim 16 wherein the current limiting element is a passive current limiting element selected from the group consisting essentially of inductors, capacitors, resistors and combinations thereof.	Roos '198 shows in FIG. 4, inductor 25, capacitors 26, 28 etc., and resistor "R". Note, 5:38-45.
Claim 27/ Element		
A	27. The electrosurgical system of claim 1 further comprising means for controlling power to the electrode terminal based on the electrical impedance between the electrode terminal and the return electrode.	Roos '198 shows in FIG. 4, inductor 25, whose input voltage is regulatable by variable tap 30, for controlling the power to electrode terminal 12 based upon impedance between it and return electrode 11. Note, 5:30-34.
Claim 30/ Element		
A	30. The electrosurgical system of claim 1 wherein the electrode terminal and the return electrode are configured to affect the electrical break down of tissue in the immediate vicinity of the electrode terminal when high frequency voltage is applied between the electrode terminal and the return electrode in the presence of electrically conducting fluid.	Roos '198 shows in FIG. 1, and generally discloses, electrode terminal 12 and return electrode 11 configured for use in an electrically conductive fluid that affect the electrical break down of tissue in the immediate vicinity of electrode terminal 12 when high frequency voltage is applied between electrode terminal 12 and return electrode 11 in the presence of electrically conducting fluid, illustrated by flow path 29.
Claim 33/ Element	33. The electrosurgical system of claim 1 wherein the electrode terminal has a distal portion configured for generating high electric field intensities sufficient to cause molecular disintegration of a body structure at the target site.	Roos '198 shows and discloses electrode terminal 12 which has a distal portion configured for generating high electric field intensities sufficient to cause molecular disintegration of a body structure at the target site. Note, 2: 37-42.
Claim 38/ Element		

Claim/ Element		
A	38. The system of claim 1 wherein the electrode terminal is configured for the cutting of tissue.	Roos '198 shows and discloses electrode terminal 12 configured for the cutting of tissue. Note, 2: 29-31.
Claim 41/ Element		
A.	41. The system of claim 1 wherein the electrode terminal and the return electrode are configured, upon the application of sufficient voltage therebetween, to affect the ablation of tissue adjacent the electrode terminal such that a portion of such tissue is volumetrically removed.	Roos '198 shows and discloses electrode terminal 12 configured with respect to return electrode 11, such that upon the application of a voltage therebetween, tissue adjacent electrode terminal 12 is ablated such that a portion of same is volumetrically removed. Note, 2:37-42 (tissue removal), 5:50-52 (tissue removal) and 6:27-29 (tissue removal to a predetermined depth).
Claim 42/ Element		
A	42. The system of claim 1 wherein the electrode terminal is disposed at the distal tip of the electrosurgical probe.	Roos '198 shows electrode terminal 12 being disposed at the distal tip of the probe. Note, 4:66-5:2, and 6:37-38.
Claim 43/ Element		
A	43. The system of claim 42 wherein the return electrode is disposed proximally of the electrode terminal on the electrosurgical probe.	Roos '198 shows return electrode 11 being disposed proximally of the electrode terminal 12 on the probe. Note, 5:3-7.
Claim 44/ Element		
A	44. The system of claim 1 wherein the electrode terminal is a flexible electrode terminal disposed at the distal tip of the probe,	Roos '198 shows and discloses electrode terminal 12 that is both flexible, and disposed at the distal tip of the probe. Note, 4:66-5:2.

Claim/ Element		
B	the flexible electrode terminal being extendable relative the distal tip of the probe.	Roos '198 shows for instance in FIG. 1, and discloses, flexible electrode terminal 12 as being extendable relative the distal tip of the probe, Note e.g., 6:12-16.
Claim 45/ Element		
A	45. An electrosurgical system for applying electrical energy to a target site on a structure within or on a patient's body, the system comprising:	Roos '198 shows and discloses a combination of structures and elements, i.e., a system, (e.g., FIG. 4) for applying electrical energy in the form of high frequency generator 15 for use in electrosurgical operations (e.g., electro resection, as in the case of bladder tumors and prostate glands, etc., 1:18-2).
B	a high frequency power supply;	Roos '198 shows the use of high frequency generator 15 and discloses use of same (e.g., 5:9).
C	an electrosurgical probe comprising a shaft having a proximal end and a distal end, an electrode terminal disposed near the distal end and a connector near the proximal end of the shaft electrically coupling the electrode terminal to the electrosurgical power supply;	Roos '198 generally shows an electrosurgical probe (FIG. 1) comprising shaft 13 having proximal and distal ends. Electrode terminal 12 is disposed near the distal end of shaft 13, with connectors schematically shown (FIGS. 4-6 & 9) near the proximal end of shaft 13 for electrically coupling electrode terminal 12 to electrosurgical power supply 15.
D	a return electrode electrically coupled to the electrosurgical power supply;	Roos '198 shows return electrode 11 electrically coupled to electrosurgical power supply 15 (e.g., FIGS. 4-6), and discloses same at 5:3-10.

Claim/ Element		
E	an electrically conducting fluid supply for directing electrically conducting fluid to the target site such that the electrically conducting fluid generates a current flow path between the return electrode and the electrode terminal.	Roos '198 shows a fluid delivery element (FIG. 1), namely the annular space bounded by the interior of shaft wall 13 and the exterior of fiber optical system 17 (4:51-57), which defines fluid path 29 (FIG. 1) for fluid flow from a fluid supply. The fluid path 29 is in electrical contact with return electrode 11 and the electrode terminal 12, which by its nature will generate a current flow path between return electrode 11 and electrode terminal 12.

Claim/ Element		
Claim 46/ Element		
A	46. An electrosurgical system as in claim 45, wherein the return electrode forms a portion of the shaft of the electrosurgical probe.	Roos '198 shows in FIGS. 7 & 8, return electrode 11 that forms a portion of the shaft 13 of the electrosurgical probe.
Claim 47/ Element		
A	47. An electrosurgical system as in claim 46 further including an insulating member circumscribing the return electrode,	Roos '198 shows in FIGS. 7 & 8, insulating members 35 & 36 circumscribing return electrode 11. Note, 7:17-20.
B	the return electrode being sufficiently spaced from the electrode terminal to minimize direct contract between the return electrode and the patient's tissue.	Roos '198 shows in FIGS. 7 & 8, return electrode 11 sufficiently spaced from electrode terminal 12 to minimize direct contact between return electrode 11 and the patient's tissue.
Claim 48/ Element		
A	48. An electrosurgical system as in claim 46, wherein the return electrode is an inner tubular member defining an axial lumen within the return electrode,	Roos '198 shows in FIGS. 7 & 8, return electrode 11 as being an inner tubular member defining an axial lumen within the return electrode 11.
B	the axial lumen having an inlet in communication with the electrically conducting fluid supply and an outlet in fluid communication with the electrode terminal.	Roos '198 shows an axial lumen having an inlet in communication with the inherent electrically conducting fluid supply ,and an outlet in fluid communication with electrode terminal 12.
Claim 55/ Element		
A	55. The electrosurgical system of claim 45 wherein the electrode terminal comprises a single active electrode disposed near the distal end of the shaft.	Roos '198 shows electrode terminal 12 being a single active electrode disposed near the distal end of the shaft 13. Note, 4:66-5:2, and 6:37-38.

Claim/ Element		
Claim 57/ Element		
A	57. The electrosurgical system of claim 45 further comprising a current limiting element for controlling current flow though the electrode terminal to inhibit power dissipation into the medium surrounding the target site.	Roos '198 shows in FIG. 4, multiple current limiting elements (i.e., inductor 25, capacitors 26, 28 etc., and resistor "R") for controlling current flow through electrode terminal 12 to inhibit power dissipation into the medium surrounding the target site. Note, 5:26-29, 31-34, and 38-45.
Claim 60/ Element		
A	60. The electrosurgical system of claim 45 further comprising means for controlling power to the electrode terminal based on the electric impedance between the electrode terminal and the return electrode.	Roos '198 shows in FIG. 4, inductor 25, whose input voltage is regulatable by variable tap 30, for controlling the power to electrode terminal 12 based upon impedance between it and return electrode 11. Note, 5:30-34.
Claim 63/ Element		
A	63. An electrosurgical system for applying electrical energy to a target site on a structure within or on a patient's body, the system comprising:	Roos '198 shows an electrosurgical system (FIG. 4) for applying electrical energy via high frequency generator 15 to a target site on a structure within or on a patient's body (i.e., a bladder or prostate as disclosed, for instance at 1:20).
B	a high frequency power supply;	Roos '198 shows the use of high frequency generator 15 and discloses use of same throughout (e.g., 5:9).
C	an electrosurgical probe comprising a shaft having a proximal end and a distal end, an electrode terminal disposed near the distal end, and a connector near the proximal end of the shaft electrically coupling the electrode terminal to the electrosurgical power supply;	Roos '198 generally shows an electrosurgical probe (FIG. 1) comprising shaft 13 having proximal and distal ends. Electrode terminal 12 is disposed near the distal end of shaft 13, with connectors schematically shown (FIGS. 4-6 & 9) near the proximal end of the shaft for electrically coupling electrode terminal 12 to the electrosurgical power supply 15.

Claim/ Element		
D	a return electrode electrically coupled to the electrosurgical power supply;	Roos '198 shows return electrode 11 electrically coupled to electrosurgical power supply 15 (e.g., FIGS. 4-6), and discloses same at 5:3-10.
E	an electrically conducting fluid supply;	Roos '198 shows a fluid delivery element (FIG. 1), namely the annular space bounded by the interior of shaft wall 13 and the exterior of fiber optical system 17 (4:51-57), which defines fluid path 29 (FIG. 1) for fluid flow from a fluid supply.
F	a fluid delivery element defining a fluid path electrically coupled to the electrode terminal for directing electrically conducting fluid to the target site and the electrode terminal to substantially surround the electrode terminal with electrically conducting fluid and to locate electrically conducting fluid between the electrode terminal and the target site.	Roos '198 shows a fluid delivery element (FIG. 1), namely the annular space bounded by the interior of shaft wall 13 and the exterior of fiber optical system 17 (4:51-57), which defines fluid path 29 (FIG. 1) for fluid flow from a fluid supply. Fluid path 29 is in electrical contact with return electrode 11 and electrode terminal 12, which by its nature will generate a current flow path between return electrode 11 and electrode terminal 16 (see also, claim 1, 7,:59 et seq.: "a space being formed between said treatment electrode and said neutral electrode which is adapted to be filled with liquid to provide electrical conductress between said electrodes.").

III. Conclusion

As shown above, this Request raises a substantial new question of patentability of claims 1-3, 14, 16, 22, 27, 30, 33, 38, 41-48, 55, 57, 60 & 63 of the Eggers '536 Patent.

A certificate of Service attesting that a copy of this Request was served on the attorney of record of the patentee is submitted herewith. Also submitted herewith is a check in the amount of $2,520.00 in compliance with 37 CFR 1.20(c).

Respectfully submitted,

Dated: 12/23/99

December 23, 1999

William C. Fuess

FUESS & DAVIDENAS

10951 Sorrento Valley Road

Suite II-G

San Diego, CA 92121-1613

FORM PTO-1449	Atty. Docket No.:	Patent No.:
		5,697,536
LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT	Inventor(s):	
	Eggers et al.	
	Issue Date	Group Art:
	12/16/97	unknown

U.S. PATENT DOCUMENTS

Examiner Initial		Document No.	Date	Name	Class	Sub Class	Filing Date If Appropriate
	AA	4,116,198	09/26/78	Roos	128	303.15	05/14/76
	AB						
	AC						
	AD						
	AE						
	AF						
	AG						
	AH						
	AI						
	AJ						
	AK						

FOREIGN PATENT DOCUMENTS

		Document No.	Date	Country	Class	Sub Class	Translation Yes	Translation No
	AL							
	AM							
	AN							

OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	AO	
	AP	
	AQ	

EXAMINER: DATE CONSIDERED:

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

United States Patent [19]

Roos

[11] **4,116,198**

[45] **Sep. 26, 1978**

[54] **ELECTRO - SURGICAL DEVICE**

[75] Inventor: **Eberhard Roos, Tuttlingen, Fed. Rep. of Germany**

[73] Assignee: **DELMA, elektro und medizinische Apparatebaugesellschaft m.b.H., Tuttlingen, Fed. Rep. of Germany**

[21] Appl. No.: **686,600**

[22] Filed: **May 14, 1976**

[30] **Foreign Application Priority Data**

May 15, 1975 [DE] Fed. Rep. of Germany 2521719

[51] Int. Cl.² A61B 17/32

[52] U.S. Cl. 128/303.15

[58] Field of Search 128/303.13–303.18

[56] **References Cited**

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Primary Examiner—Lee S. Cohen

[57] **ABSTRACT**

Electro-surgical device with an insulated cable which can be passed through an endoscope, to which can be connected the pole of a high frequency generator, said pole being insulated from earth potential and on whose end facing the body cavity is provided a small-area treatment electrode projecting from the endoscope, said treatment electrode cooperating with a large-area neutral electrode connected to the other pole of the high frequency generator which is insulated from earth potential in such a way that due to the high current density in the area of the treatment electrode, a generation of heat takes place which is adequate for separating or coagulating tissue, wherein the large-area neutral electrode is arranged in the vicinity of the treatment electrode and is connected with the other pole of the high frequency generator by means of an insulated cable which can also be passed through the endoscope.

20 Claims, 9 Drawing Figures

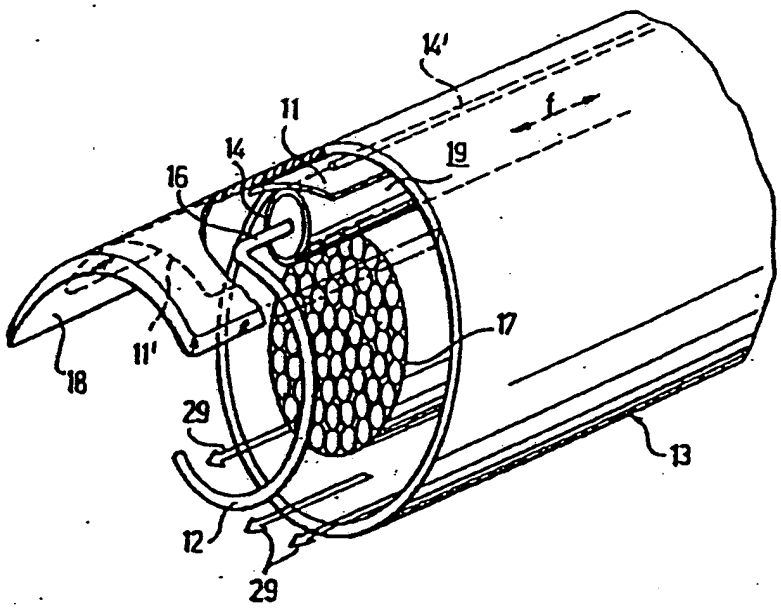


Fig.1

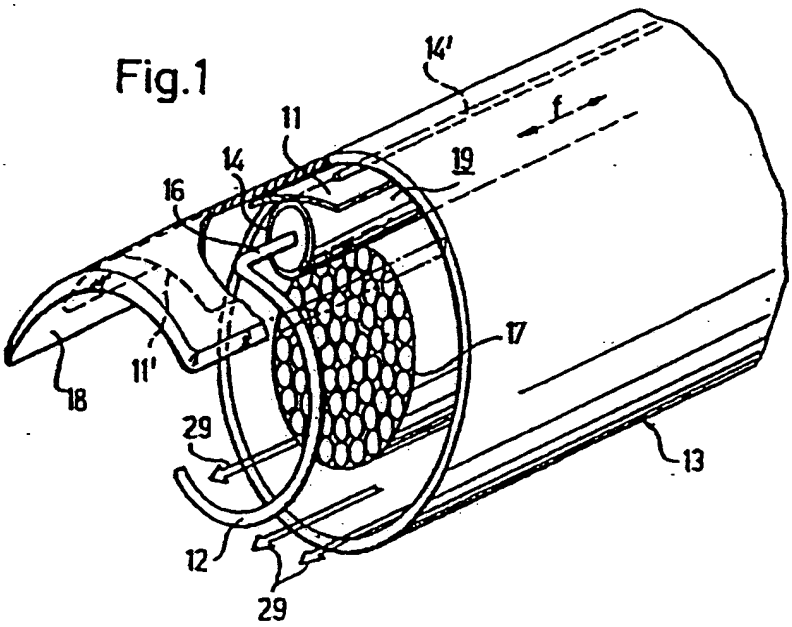
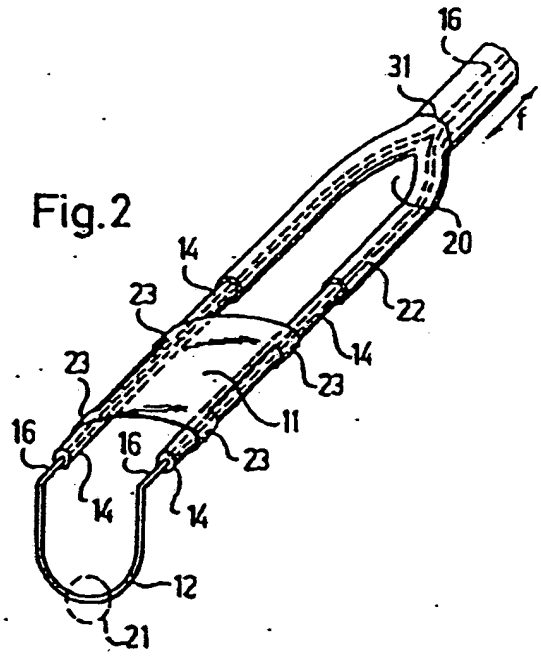

14'
11
f
14
19
16
17
18
11'
29
13
12
29

Fig.2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14
22
23
14
23
23
11
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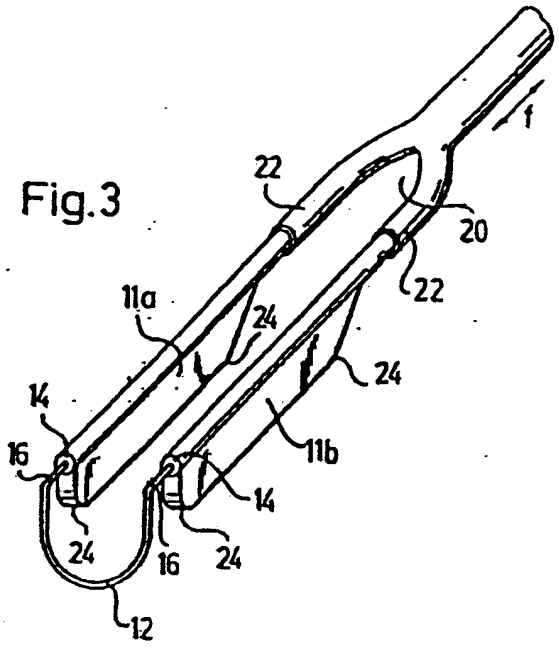
23
16
14
14
12
21

Fig.3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22
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22
11a
24
24
14
16
11b
14
24
16
24
12

Fig.4

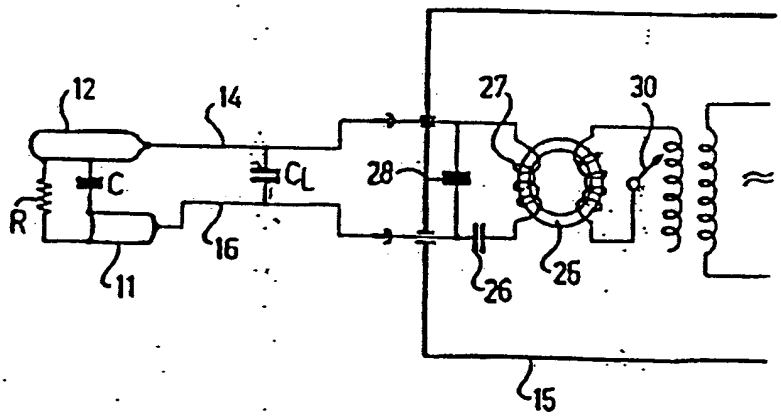

12
14
27
30
C
C1
28
R
16
11
26
25
15

Fig.5

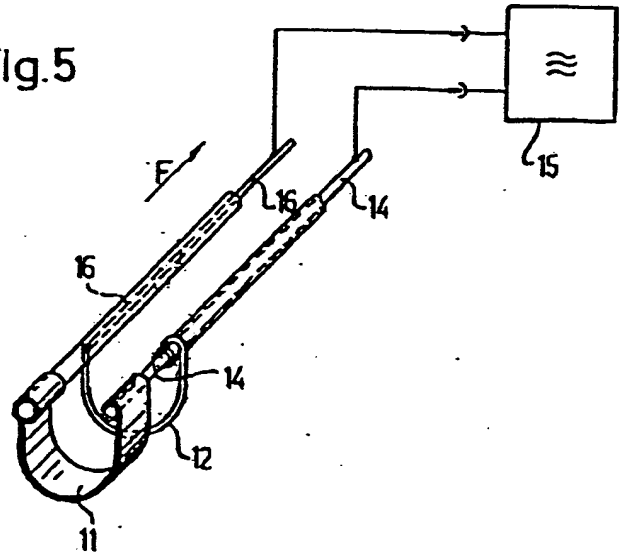


Fig.6

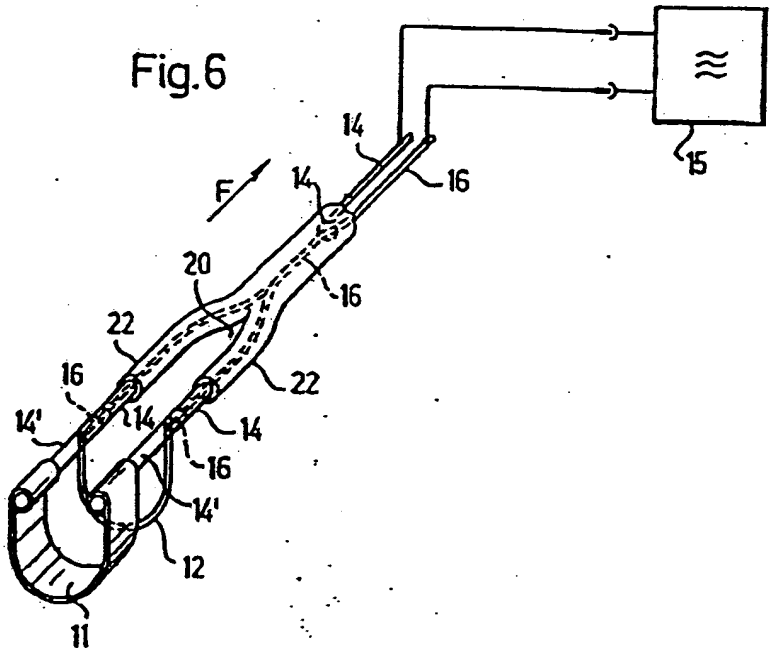


Fig.7

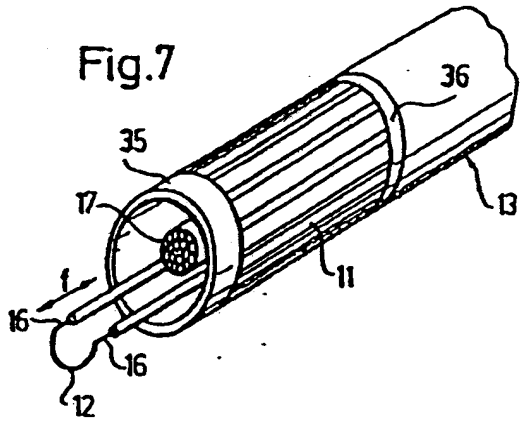


Fig.8

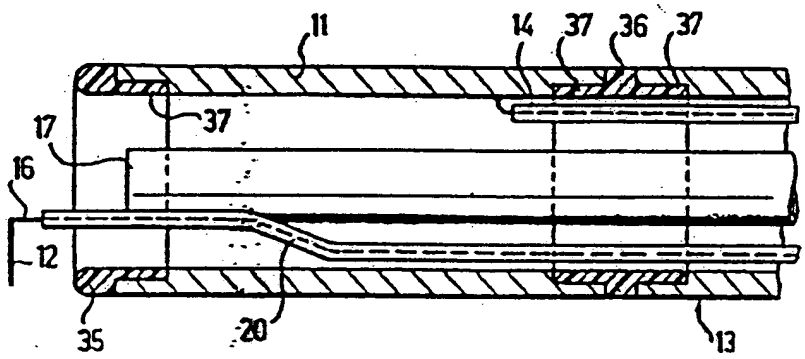
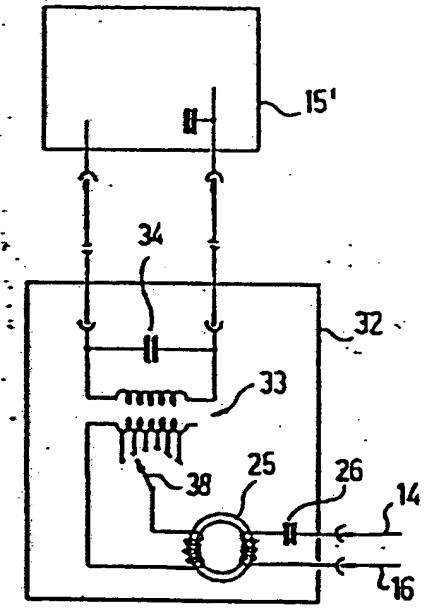


Fig.9



ELECTRO - SURGICAL DEVICE

BACKGROUND OF THE INVENTION

The invention relates to an electro-surgical device with an insulated cable which can be passed through an endoscope, to which can be connected the pole of a high frequency generator, said pole being insulated from earth potential and on whose end facing the body cavity is provided a small-area treatment electrode projecting from the endoscope, said treatment electrode cooperating with a large-area neutral electrode connected to the other pole of the high frequency generator which is insulated from earth potential in such a way that due to the high current density in the area of the treatment electrode, a generation of heat takes place which is adequate for separating or coagulating tissue.

Electro-surgical devices of this type permit electro-surgical operations of the filled bladder (electro-resection, e.g. of bladder tumors and the prostate glands) using endoscopes, particularly resectoscopes and cystoscopes.

The high degree of development in the endoscope field has resulted in operations in the bladder and on the prostate glands using these instruments and by means of electro-surgery have become the most commonly used operating procedure.

In known devices of this type, high frequency alternating current is fed via an earthed neutral electrode on the one hand and via a sparking ball or cutting loop well insulated relative to the outer shaft of the endoscope on the other to the operating area for coagulation purposes in the case of hemorrhages. Due to the relatively small area of the cutting loop compared to the area of the neutral electrode applied externally to the patient's body a very high current density occurs in the area of the cutting loop which results in heat generation in the tissue linked with the bursting of the tissue cells through steam generation and consequently a separation of the tissues. For the desired cutting or coagulating effects, the necessary power values of the high frequency current applied vary between 120 and 150 W.

As the leads from the high frequency generator to the cutting electrode have to be passed through the metallic endoscope, the distances between the high frequency-carrying lead and the remaining metal parts of the endoscope insulated therefrom are so small that capacitances of considerable size exist between these metal parts. Thus, to a certain extent, the endoscope forms a capacitor via which part of the applied capacity flows away as leakage current onto the tissue engaging with the metal endoscope shaft. A further, still larger portion of the applied capacity flows from the cutting loop via the washing water directly to the metal parts of the endoscope shaft located in the washing water flow and from there to the engaging tissue. Thus, uncontrollable electrical conditions in the urethral tissue engaging with the endoscope and the unequal distribution of lubricants with insulating properties on the endoscope shaft can cause critical current densities when the leakage current passes to the urethra and this results in burns.

These difficulties would not be eliminated by coating the endoscope shaft with tubes of high-grade insulating material, because the slightest damage to the shaft insulation due to the very high current densities occur during the passage of the leakage current would, in fact, increase the danger of burning due to the damage. However, if the endoscope shaft insulation remains intact, the entire leakage current is led off to the points where the operator is in contact with the endoscope leading to burns to the operator's face or to the eye in contact with the metal escutcheons of the transparent optics.

Neutral electrode isolation from earth potential cannot prevent the passage of the leakage currents to the operator. As the neutral electrode acts as an opposite pole to the cutting or coagulation electrode between the patient and the earthed operating table, it is capacitively connected to earth potential. Therefore, the cutting loop and the leakage current flown therefrom together with its voltage are earthed. Since, in any case, the operator largely carries the earth potential, the passage of the leakage current to the operator cannot be avoided by the measures in question.

BRIEF SUMMARY OF THE INVENTION

The problem of the invention is therefore to provide an electro-surgical device of the type indicated hereinbefore where undesired burns to the urethra and the operator are effectively avoided.

According to the invention, this problem is solved in that the large-area neutral electrode is arranged in the vicinity of the treatment electrode and is connected with the other pole of the high frequency generator by means of an insulated cable which can also be passed through the endoscope. In this way, potential compensation takes place in a spatially very narrowly defined zone. Both the treatment electrode, preferably constructed as a cutting loop and the neutral electrode carry no potential to earth. Leakage current does not flow to the endoscope shaft either from the high frequency lead to the treatment electrode or from the lead to the neutral electrode. Due to the existing capacitance, leakage currents only flow between the leads, but these do not have any external effects.

However, due to the small-area construction of the treatment electrode, a high current density is obtained there, which is adequate for tissue separation or coagulation, whereas the neutral electrode arranged in the immediate vicinity has such a large area that undesired heating is avoided there.

According to a preferred embodiment, the two feed leads comprise a coaxial cable, whose shield forms one conductor and is insulated relative to the endoscope. Thus, the two high frequency leads for the treatment and neutral electrode form a structural unit, which whilst taking up only a small amount of space, can be simply passed through the endoscope together with the optical and washing portions.

In general, the treatment electrode should be in loop form so that the operator's field of vision is uninterrupted.

According to a further embodiment, the centre conductor of the coaxial cable at the front projects above the shield and at this point passes into the treatment electrode. It is thereby particularly advantageous if the shield is constructed as a rigid sleeve and in such a way that the treatment electrode can be moved backwards and forwards relative to the endoscope via the coaxial cable. Thus, in this embodiment, the coaxial cable at the same time forms the support and operating member for the treatment electrode.

The relatively large neutral electrode is advantageously directly fixed to the coaxial cable shield. In this way the neutral electrode can be mounted reliably and immovably in an inexpensive and uncomplicated manner.

Advantageously, the neutral electrode is constructed as an elongated metal sheet slightly curved about the endoscope shaft and extending on either side over the coaxial cable.

According to a further advantageous embodiment, the endoscope has a plastic extension extending over a small portion only of its periphery, whereby the treatment electrode can be moved backwards and forwards beneath the said extension. This plastic extension has the advantage that the washing liquid can be satisfactorily guided and tissue which is not to be treated can be kept away from the treatment electrode. According to the invention, this extension can be used so that the large-area neutral electrode is fixed in insulated manner relative to the endoscope on the inside of the extension. The neutral electrode is then preferably connected with the high frequency generator by an insulated cable secured in the endoscope. In this case, only the other conductor with its insulation and treatment electrode is axially movable.

According to a particularly preferred embodiment, the coaxial cable has a bifurcation just before the body-side end of the endoscope and the two inner conductors eminating from the bifurcation are interconnected by a loop forming the treatment electrode. This construction is particularly stable due to the symmetry conditions resulting from the bifurcation, whereby at the same time the operator still has good visibility through the cutting loop forming the treatment electrode.

If the treatment electrode is used for coagulation purposes, a coagulation sparking ball is fitted to the treatment electrode.

The coaxial cable is advantageously surrounded by an insulating lead so as to prevent any connection of the endoscope metal with the high frequency voltage. Preferably, the insulating sleeve of the bifurcated coaxial cable is also bifurcated, but it extends only to just in front of the neutral electrode.

In the case of the bifurcated coaxial cable, the neutral electrode is preferably an elongated metal sheet, bent slightly around the endoscope shaft and extending from one branch of the bifurcation to the other. The sheet can have projections at the four corners which are placed around the shields. Depending on the degree of placing around and also clamping, any desired fixing of the neutral electrode to the coaxial cable can be obtained.

The current density in the area of the operating zone is advantageously influenced if the neutral electrode terminates at a distance from the end of the shield.

According to a further advantageous embodiment, the neutral electrode comprises two partial electrodes extending in the direction of the loop away from the two arms of the bifurcation. Preferably, the partial electrodes do not extend quite as far from the shields as the loop. At the front and rear ends the sheets preferably have rounded portions.

As a result of the slide-like construction, the operator can reliably guide the endoscope by placing the slide-like sheet projections on the tissue to then be removed. As is known, the endoscope is operated in such a way that the cutting loop is moved forwards relative to the endoscope, made live and then slowly retracted, whereby the tissue is removed by the heating on the cutting loop.

As stated hereinbefore, the treatment electrode and neutral electrode are appropriately so shaped and positioned that the illumination, vision and washing operations are not impaired by the endoscope.

Advantageously, the leads are inductively connected to the high frequency generator, whereby advantageously, a capacitor for filtering out low frequency voltage portions is preferably provided in one lead. This, in advantageous manner avoids faradic effects in the muscular system of the patient.

A capacitor is appropriately connected in parallel to the output winding of the transmitter which with the inductor of the latter forms an oscillating circuit which is tuned in such a way that the attenuation in the oscillating circuit formed by the leads, treatment electrode and neutral electrode is minimal.

BRIEF DESCRIPTION OF THE DRAWINGS

Other and further objects of the present invention will be apparent from the following description and claims and are illustrated in the accompanying drawings which, by way of illustration show preferred embodiments of the present invention and the principles thereof and what are now considered to be the best modes contemplated for applying these principles. Other embodiments of the invention embodying the same or equivalent principles may be used and structural changes may be made if desired by those skilled in the art without departing from the invention and the scope of the appended claims.

In the drawings show:

FIG. 1 a schematic, greatly enlarged perspective view of the front end of an endoscope equipped with the electro-surgical device according to the invention.

FIG. 2 a perspective view of a further embodiment of the electro-surgical device according to the invention, without the endoscope surrounding the same.

FIG. 3 a further embodiment of the electro-surgical device according to the invention, once again without a surrounding endoscope.

FIG. 4 a schematic circuit diagram of the electro-surgical device according to the invention with a particularly suitable high frequency generator.

FIGS. 5 and 6 perspective views of two further advantageous embodiments

FIGS. 7 and 8 a perspective view and an axial section of a further advantageous embodiment.

FIG. 9 a schematic circuit diagram of an additional device for the device according to the invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

According to FIG. 1, an endoscope 13 is axial traversed in conventional manner by a fibre optical system 17, which is spaced relative to the sides of the endoscope 13, in such a way that washing liquid can pass through there (arrow 29) and there still remains space for the axial insertion of an electro-surgical treatment device.

According to the invention, this electro-surgical treatment device comprises a coaxial cable 19 with rigid metallic shield 14 and an inner conductor 16 axially inserted together with the fibre optical system 17. Inside the metallic shaft of the endoscope 13, the shield 14 is covered in not shown manner with an insulating sleeve 21, shown in the case of the constructions of FIGS. 2 and 3.

At the front, inner conductor 16 projects somewhat from the coaxial cable 19 and passes into the treatment electrode 12, which in general comprises a loop ensur-

ing free visibility for the operator via the fibre optical systems 17.

The opposite electrode for the cutting electrode 12 is formed by a neutral electrode 11 fixed in electrically conductive manner to shield 14 and which is curved somewhat about the endoscope shaft, having a rectangular, elongated form shown in FIG. 1. Inner conductor 16 and shield 14 are connected, as shown in FIG. 4 to the two poles of a high frequency generator 15 which are not at earth potential.

At the front end of the metal shaft of the endoscope 13 is fixed a plastic extension 18, which is rounded and extends in the manner shown in FIG. 1, so as not to impair insertion, for example into the urethra. As the plastic extension 18 is an insulating body, the large-area neutral electrode 11' can also be fitted to the inside. It is then appropriately connected with the associated pole of the high frequency generator via a separate insulated conductor 14' in the endoscope, inside of via the shield 14.

As a result of the construction according to the invention, a high frequency field is only formed between shield 14 and inner conductor 16, as well as between neutral electrode 11 and treatment electrode 12, as is shown schematically in FIG. 4 by capacitors C_L and C. Due to the current conduction through the tissue fluid and tissue itself, a true resistor R is also conceivable parallel to the capacitor between neutral electrode 11 and treatment electrode 12.

The supply to connect neutral electrode 11 and the treatment electrode 12 takes place by the inductive coupling of a high frequency voltage by means of a transformer 25, whose input voltage is regulatble by a variable tap 30. Due to the inductive coupling, the output lines 14 and 16 are galvanically isolated from earth potential.

A capacitor 26 connected in lead 16 is used for filtering out the low frequency current and therefore avoids faradic effects in the muscular system of the patient. A capacitor 28 connected in parallel to the output winding 27 of transformer 25 and behind capacitor 26 forms with the output winding an oscillating circuit tuned in such a way that the attenuation in the oscillating circuit formed from C_L, C and R as well as the inductors of lines 14, 16 is minimal.

As a result of the construction according to the invention, the leakage currents only flow between lines 14, 16 and therefore do not reach the metal shaft of endoscope 13. Thus, larger current densities such as are necessary for tissue separation or coagulation only occur outside the endoscope in the operating area.

Therefore, the danger of heating outside the desired area, as well as burns to the operator is reliably avoided.

FIG. 2 shows a particularly advantageous embodiment of the electro-surgical device according to the invention in which both the inner conductor 16 and the shield 14 have a bifurcation 20. I, the same way, the insulating sleeve drawn over the shield 14 is bifurcated. The production of such a bifurcation is advantageously obtained by a welded joint at point 31 indicated by a line.

As a result of the bifurcation shown in FIG. 2, a cutting loop 12 can be arranged in the shown manner between the two inner conductors 16 emmating at the end. If the treatment electrode is to be used for coagulation, a coagulation sparking ball 21 can be provided on loop 12.

The construction of FIG. 2 is particularly well suited to the arrangement of a relatively large-area neutral electrode 11 which appropriately extends between the shields 14 of the two branches of the bifurcation 20, being slightly bent about the endoscope shaft. At the end, the neutral electrode 11 has projections 23 which are securely placed around the shields 14 for securing neutral electrodes 11 and for supplying the same with voltage. The metal sheeting forming the neutral electrode simultaneously constructionally reinforces the bifurcation 20, so that the guidance of the treatment electrode 12 by the operator is aided. As is known, the axial movement of the electro-surgical device in the direction of the double arrow *f* takes place by operating a pistol-like handle on endoscope 13, not shown in the drawing.

A further advantageous embodiment is shown in FIG. 3 where the neutral electrode is broken up into two partial electrodes 11*a*, 11*b*, which in the represented manner are soldered or welded to the shields 14 in such a way that the partial electrodes extend in the same direction as cutting loop 12. Rounded portions 24 are provided at both ends. The partial electrodes 11*a*, 11*b* applied to the shields 14 in this way thus additionally form slide-like support, by means of which the electro-surgical device can be placed on the tissue to be removed. This not only ensures a reliable guidance of the device but also ensures that the tissue is removed to the predetermined depth. The electrical advantages of limiting current conduction to the operating area are completely maintained.

FIG. 5 shows a further advantageous embodiment, whereby only the front part of the electro-surgical device without the endoscope is shown. In this embodiment, two insulated cables with inner conductors 14, 16 are passed from high frequency generator 15 through the endoscope. At the front end are successively arranged the cutting loop 12 and the neutral electrode 11 constructed as a steel band. The cutting loop 12 is electrically conductively connected with the inner conductor 16, but at the other end is only fixed to the insulation surrounding the conductor 14. Conversely, the steel band 11, whose shape is similar to the cutting loop 12, is connected in electrically conductive and mechanically secure manner with the inner conductor 14, whilst the opposite end is mechanically secured to the insulation of the inner conductor 16. Since, according to the invention, the steel band 11 has the same radius as the wire loop, on retracting the loop 12 in the direction of arrow F, the band does not form an obstacle to the tissue portions removed by the loop. The neutral electrode 11 in the form of the steel band rests on the tissue in large-area form, so that good electrical contact is ensured.

FIG. 6 shows an embodiment which is substantially the same as FIG. 5, whereby however, a bifurcated coaxial cable, similar to FIGS. 2 and 3 is used. The wire loop 12 is once again fixed to the inner conductors 16, whilst the neutral conductor 11 in band form is mechanically secured to extensions 14' electrically connected with the shield 14.

In the embodiment according to FIGS. 7 and 8, the front portion of endoscope 13 itself or a coaxial connection attached thereto at the front is constructed as the neutral electrode 11. To this end, the front portion is electrically insulated relative to the rear portion or the front-fitted connection from endoscope 13 by an intermediately inserted insulating ring 36. The cutting loop 12 can at the front be passed out of the neutral electrode

11 in one of the above-described manners. In the present embodiment, two leads 16 pass outwards from the cylindrical neutral electrode 11, which at 20 are combined to form a single cable, leading to the rear end of endoscope 13. The neutral electrode 11 is connected via a further insulated cable 14 to the high frequency generator 15 not shown in FIGS. 7 and 8.

It is also important in the case of the embodiments of FIGS. 7 and 8 that the cutting loop extends radially up to an insulating ring 35 mounted at the front on the neutral electrode 11 and can be retracted up to this. In this way, the front edge of the endoscope shaft, namely the front edge of the insulating ring 35 serves as a support for the cutting loop 12, so that the material is reliably removed therefrom. Therefore, as shown the insulating ring 35 must be rounded at the front.

Preferably, the insulating rings 35, 36 have axial attachments 37 with a reduced external diameter, by means of which a mechanically secure fixing to the metal tubes is ensured.

FIG. 9 shows an additional device 32, by means of which a conventional high frequency surgical apparatus 15' with an earthed output terminal can be made usable for the purposes of the invention. The additional device 32 connected to the high frequency apparatus 15' has at the inlet a transformer 33 with parallel-connected capacitor 34 for tuning to the resonant frequency of the output circuit of the high frequency apparatus 15'. The output winding of transformer 33 is preferably regulatable by means of a loop arm 38 in such a way that the inductive output transformer 25 can receive voltages of varying sizes.

Via a capacitor 26, the output winding of transformer 25 is applied to the two output terminals of the additional device 32, where the leads 14, 16 can be applied.

In this way the high frequency apparatus 15' acquires an output with fluctuating potential, as is necessary for the connection of the electro-surgical device according to the invention.

The invention is not limited to the embodiments described and represented hereinbefore and various modifications can be made thereto without passing beyond the scope of the invention.

What is claimed is:

1. In combination: an endoscope having an endoscope body of substantially tubular shape, and an electro-surgical device comprising a treatment electrode projecting at one end from said endoscope body and a neutral electrode arranged adjacent said treatment electrode, insulated cable means for connecting said treatment electrode to one pole of a high-frequency generator, and means for connecting said neutral electrode to the other pole of a high-frequency generator, said endoscope body having an insulating projection extending over a portion of the periphery of said endoscope body at said one end and having a front edge, said neutral electrode being located within said endoscope body and spaced a distinct distance inwardly from said front edge, a space being formed between said treatment electrode and said neutral electrode which is adapted to be filled with liquid to provide electrical conductance between said electrodes.

2. The combination of claim 1, wherein said insulated cable means and said means for connecting said neutral electrode to said other pole comprise coaxial cable means with shielding means forming one of said connecting means and being insulated relative to said endoscope body.

3. The combination according to claim 2, wherein said shielding means is constructed as a rigid sleeve in which said treatment electrode is adapted to be moved back and forth relative to said endoscope body through said coaxial cable means.

4. The combination according to claim 2, wherein said neutral electrode is fixed directly to said shielding means of said coaxial cable means.

5. The combination according to claim 4, wherein the neutral electrode is constructed as an elongated metal sheet slightly bent within said endoscope body and extending over said coaxial cable means.

6. The combination according to claim 2, comprising an insulating sleeve surrounding said coaxial cable means.

7. The combination according to claim 6, wherein said insulating sleeve is bifurcated and extends approximately to said neutral electrode.

8. The combination according to claim 7, wherein said neutral electrode is an elongated metal sheet slightly bent within said endoscope body and extending from one branch of said bifurcated insulating sleeve to the other.

9. The combination according to claim 8, wherein said sheet has projections at its four corners, two each of which are placed around the respective branches of said bifurcated sleeve.

10. The combination according to claim 2, wherein said neutral electrode terminates at a distance from said shielding means.

11. The combination according to claim 1, wherein said neutral electrode is secured to and insulated from said endoscope body on the inside of said insulating projection.

12. The combination according to claim 1, wherein said means for connecting said neutral electrode to said high-frequency generator is an insulated conductor secured in said endoscope body.

13. The combination according to claim 2, wherein said coaxial cable means has a bifurcation at that end of the endoscope body adjacent said projection, two inner conductors eminating from said bifurcation, and a loop interconnecting said two inner conductors and forming said treatment electrode.

14. The combination according to claim 1, wherein a coagulation sparking ball is fitted to said treatment electrode.

15. The combination according to claim 1, comprising a high-frequency generator, and wherein said cable means and said connecting means are inductively coupled to said high-frequency generator.

16. The combination according to claim 15, wherein a capacitor is connected in one of said cable means and said connecting means for filtering out low-frequency voltage.

17. The combination according to claim 15, wherein said generator comprises a transformer with an output winding having an inductor, a capacitor being connected parallel to said output winding and forming an oscillating circuit with said inductor, said circuit being tuned such that the attenuation in said circuit formed by said cable means, said connecting means, treatment electrode and neutral electrode is minimal.

18. The combination according to claim 15, comprising means for potential isolation connected between said high-frequency generator and said cable means and said connecting means respectively.

19. The combination according to claim 18, wherein said potential isolation means comprises a transformer, a capacitor connected parallel to said transformer, said high-frequency generator having an output circuit, said transformer and said output circuit being tuned in resonance.

20. The combination according to claim 19, comprising an inductive transformer connected to said transformer, said cable means and said connecting means being connected to said inductive transformer.

* * * * *

United States Patent [19]

Eggers et al.

[54] **SYSTEM AND METHOD FOR ELECTROSURGICAL CUTTING AND ABLATION**

[75] Inventors: **Philip E. Eggers**, Dublin, Ohio; **Hira V. Thapliyal**, Los Altos, Calif.

[73] Assignee: **Arthrocare Corporation**, Sunnyvale, Calif.

[21] Appl. No.: **746,800**

[22] Filed: **Nov. 18, 1996**

Related U.S. Application Data

[60] Division of Ser. No. 485,219, Jun. 7, 1995, which is a continuation-in-part of Ser. No. 446,767, Jun. 2, 1995, which is a continuation-in-part of Ser. No. 59,681, May 10, 1993, abandoned, which is a continuation-in-part of Ser. No. 958,977, Oct. 9, 1992, Pat. No. 5,366,443, which is a continuation-in-part of Ser. No. 817,575, Jan. 7, 1992, abandoned.

[51] Int. Cl.[6] A61M 37/00

[52] U.S. Cl. 604/114; 604/22

[58] Field of Search 604/22, 43, 48, 604/113, 114, 264, 271, 280; 606/31, 28, 29, 39, 41, 45

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[11] Patent Number: 5,697,536

[45] Date of Patent: Dec. 16, 1997

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Primary Examiner—Manuel Mendez

Attorney, Agent, or Firm—Townsend and Townsend and Crew LLP

[57] ABSTRACT

An electrosurgical probe (10) comprises a shaft (13) having an electrode array (12) at its distal end and a connector (19) at its proximal end for coupling the electrode array to a high frequency power supply (28). The shaft includes a return electrode (55, 56) recessed from its distal end and enclosed within an insulating jacket (18). The return electrode defines an inner passage (83) electrically connected to both the return electrode and the electrode array for passage of an electrically conducting liquid (50). By applying high frequency voltage to the electrode array and the return electrode, the electrically conducting liquid generates a current flow path between the target site and the return electrode so that target tissue may be cut or ablated. The probe is particularly useful in dry environments, such as the mouth or abdominal cavity, because the electrically conducting liquid provides the necessary return current path between the return electrode and the target site.

64 Claims, 10 Drawing Sheets

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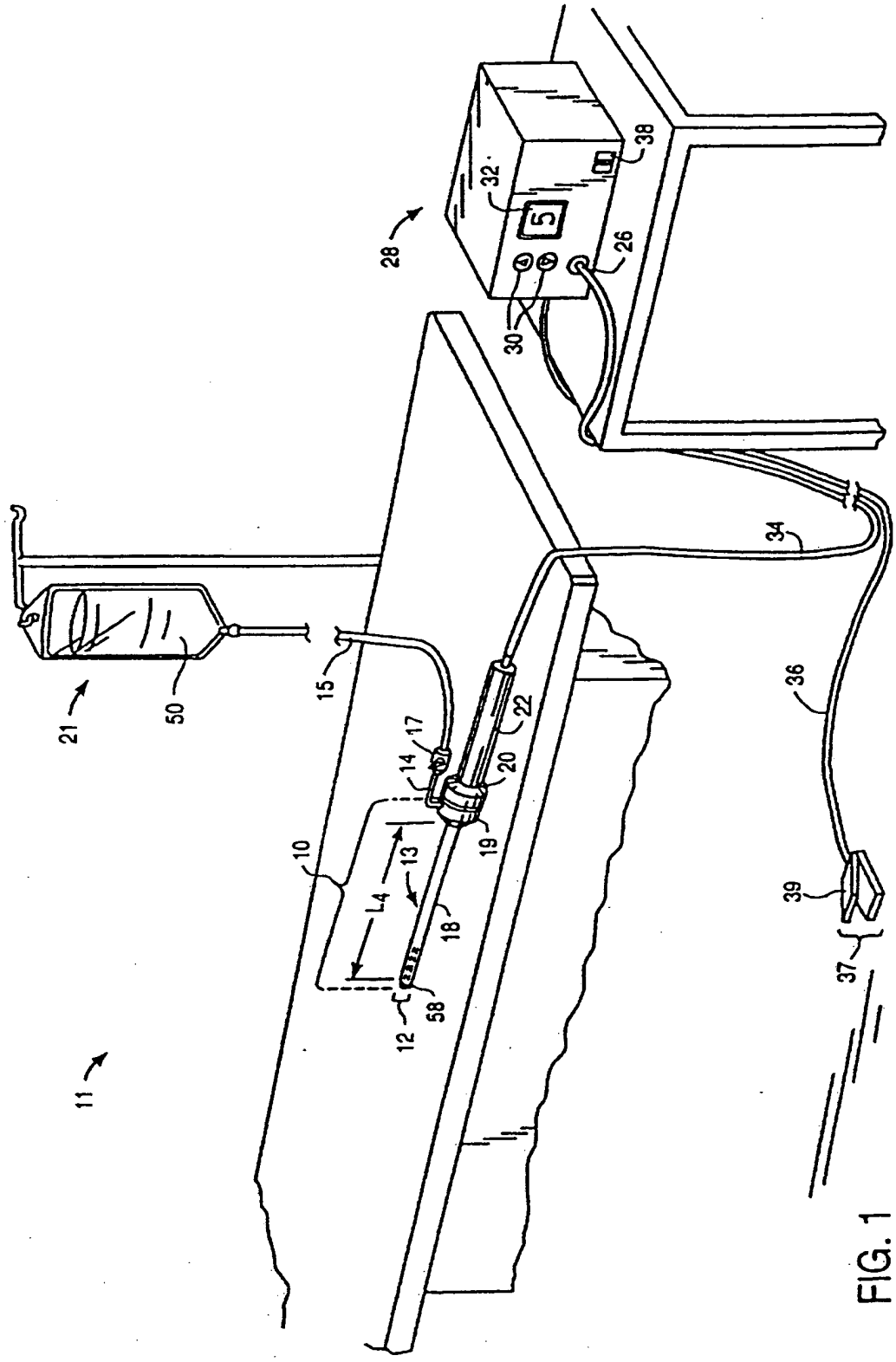

FIG. 1

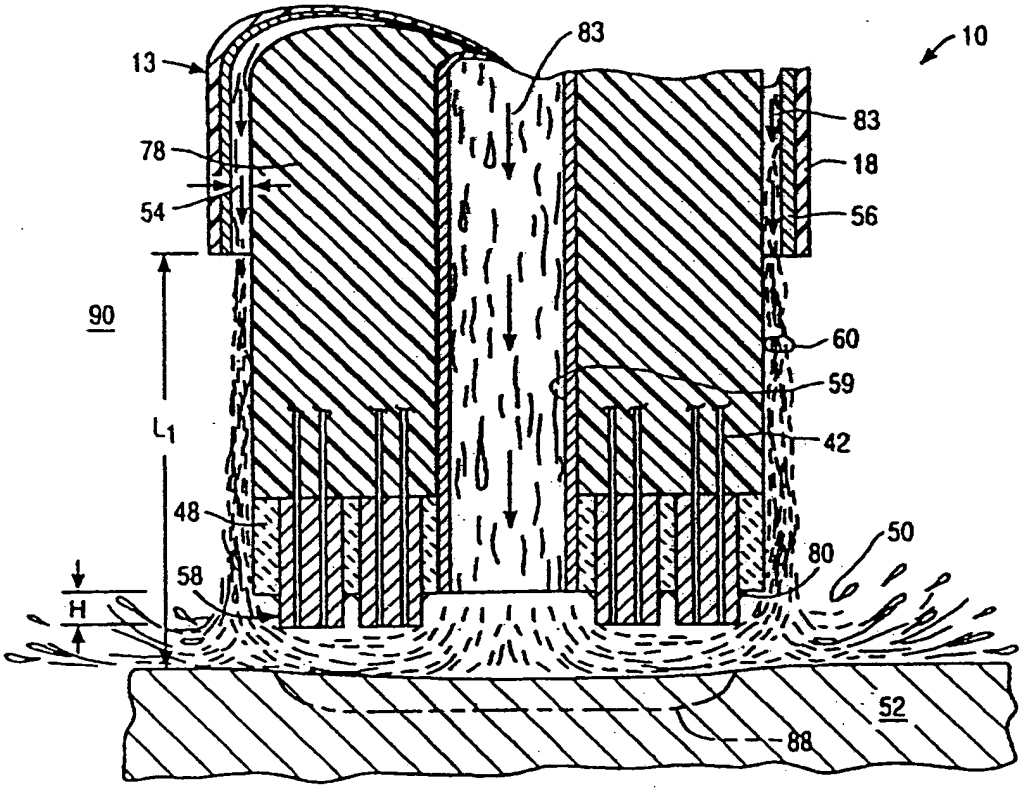
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FIG. 2A

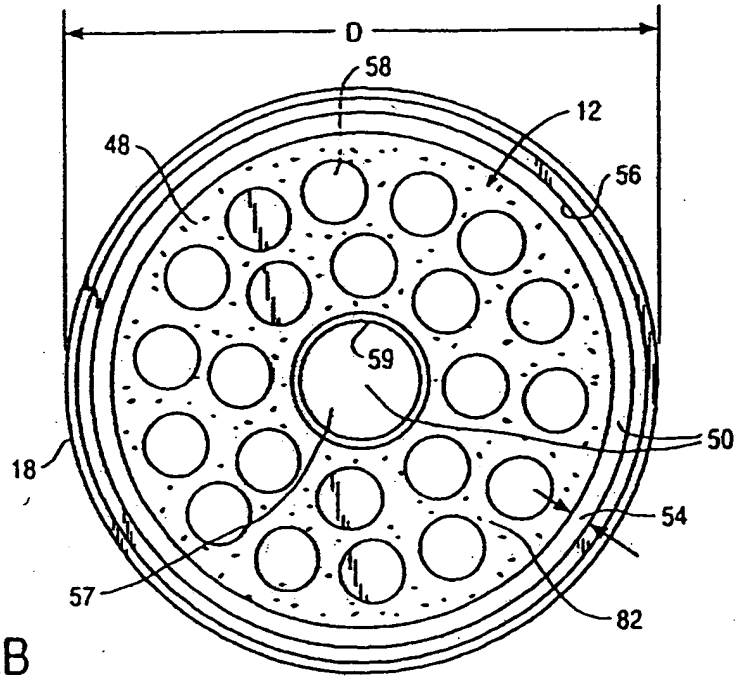
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FIG. 2B

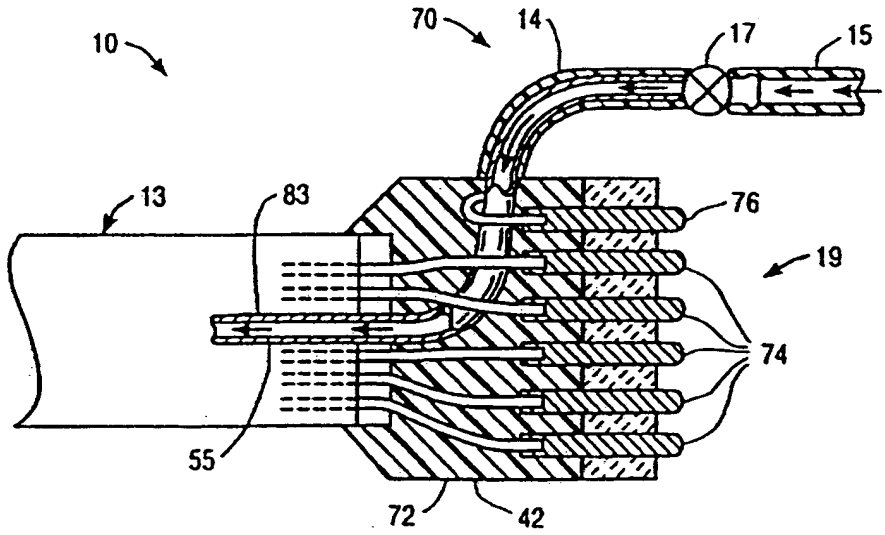
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FIG. 2C

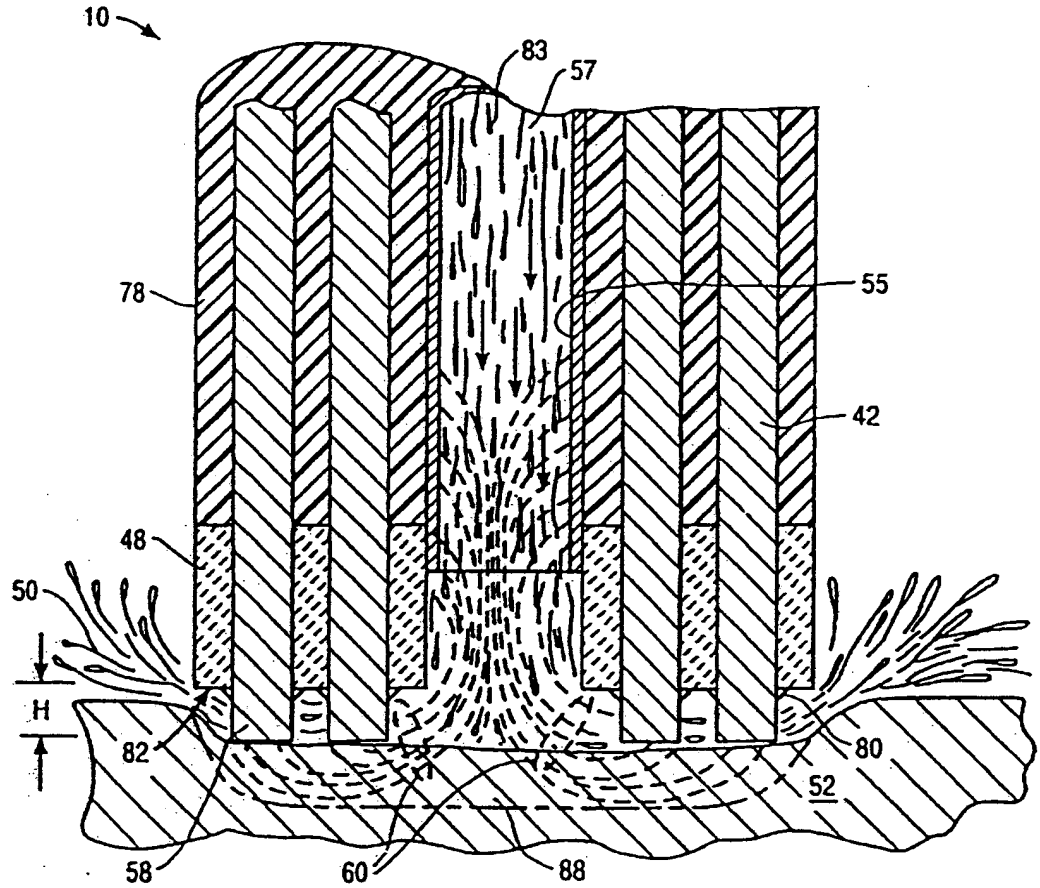
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FIG. 3

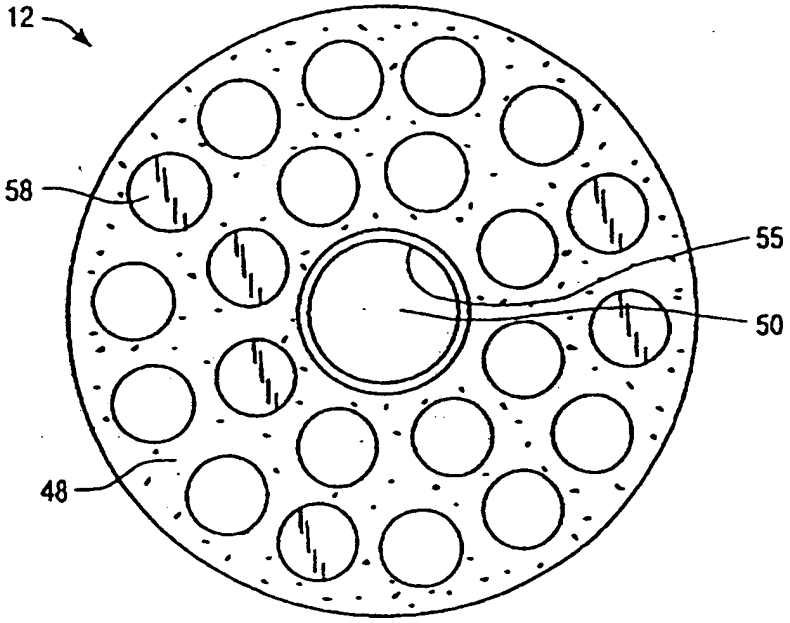

FIG. 4

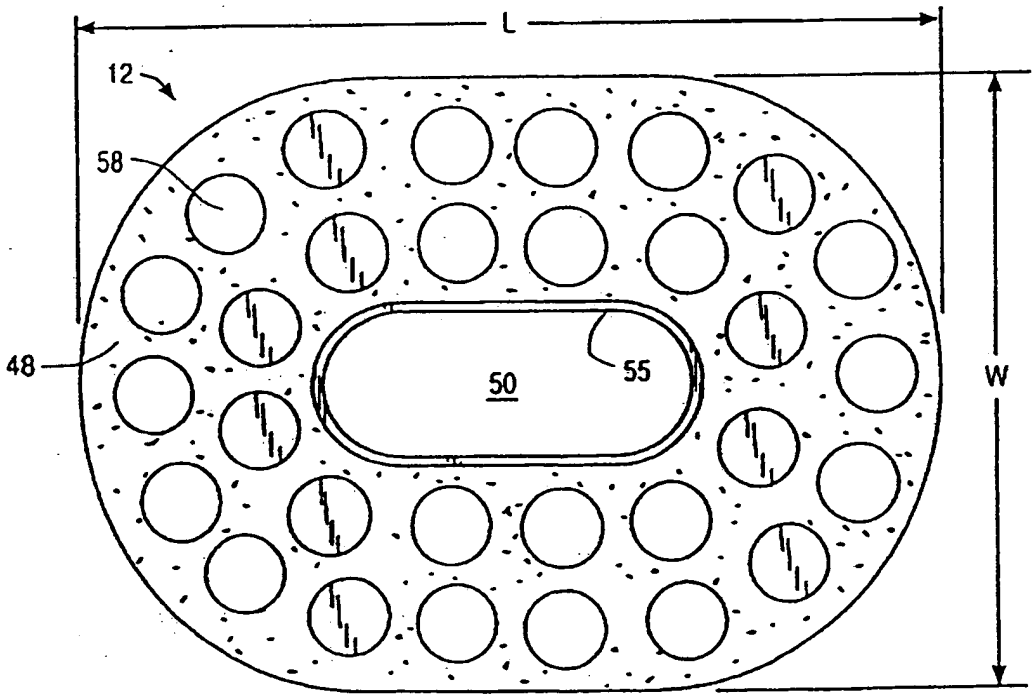

FIG. 5

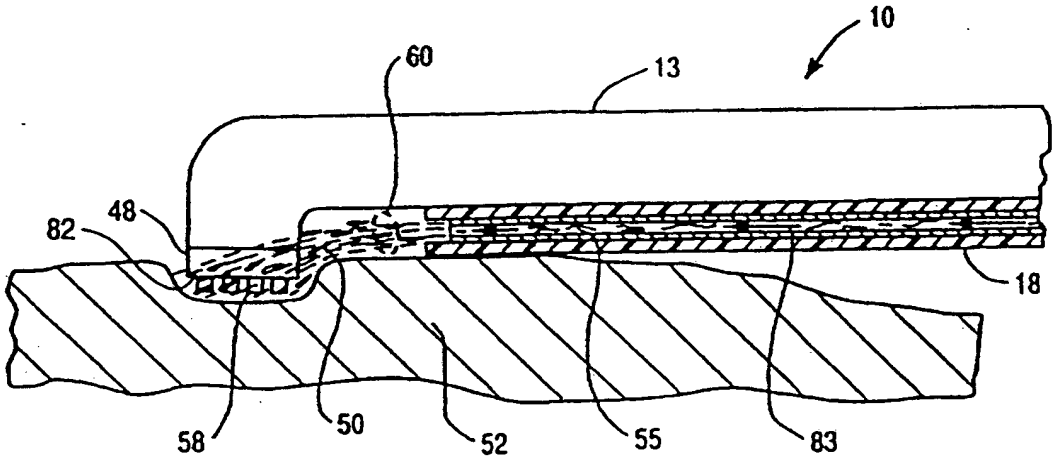

FIG. 6

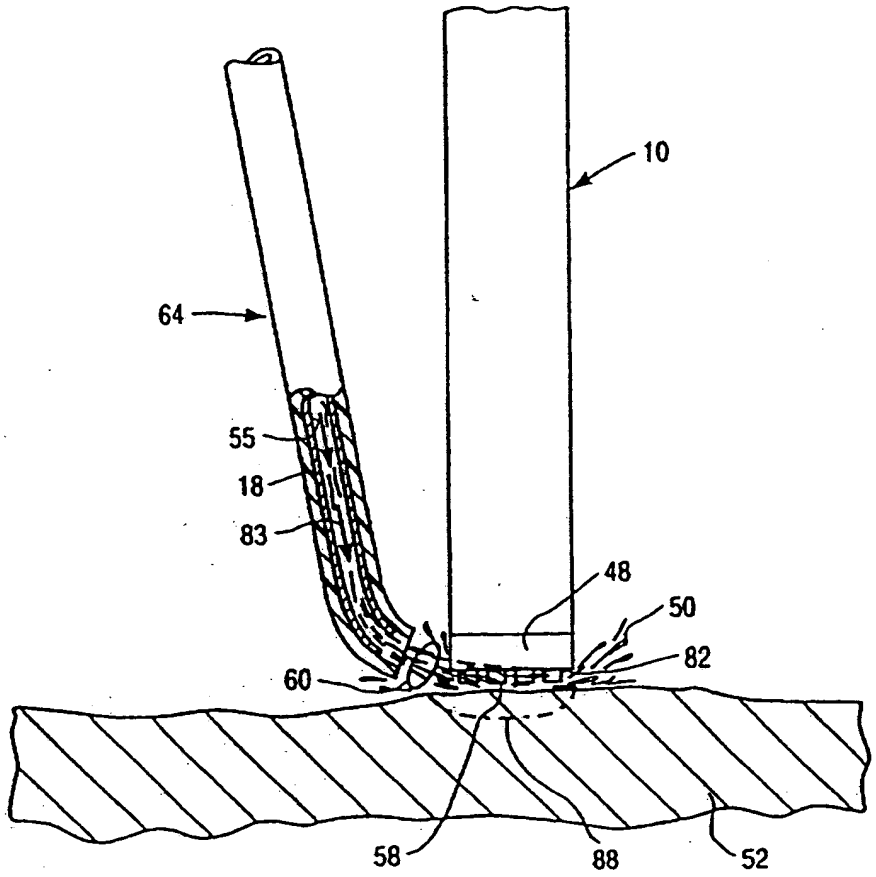

FIG. 7

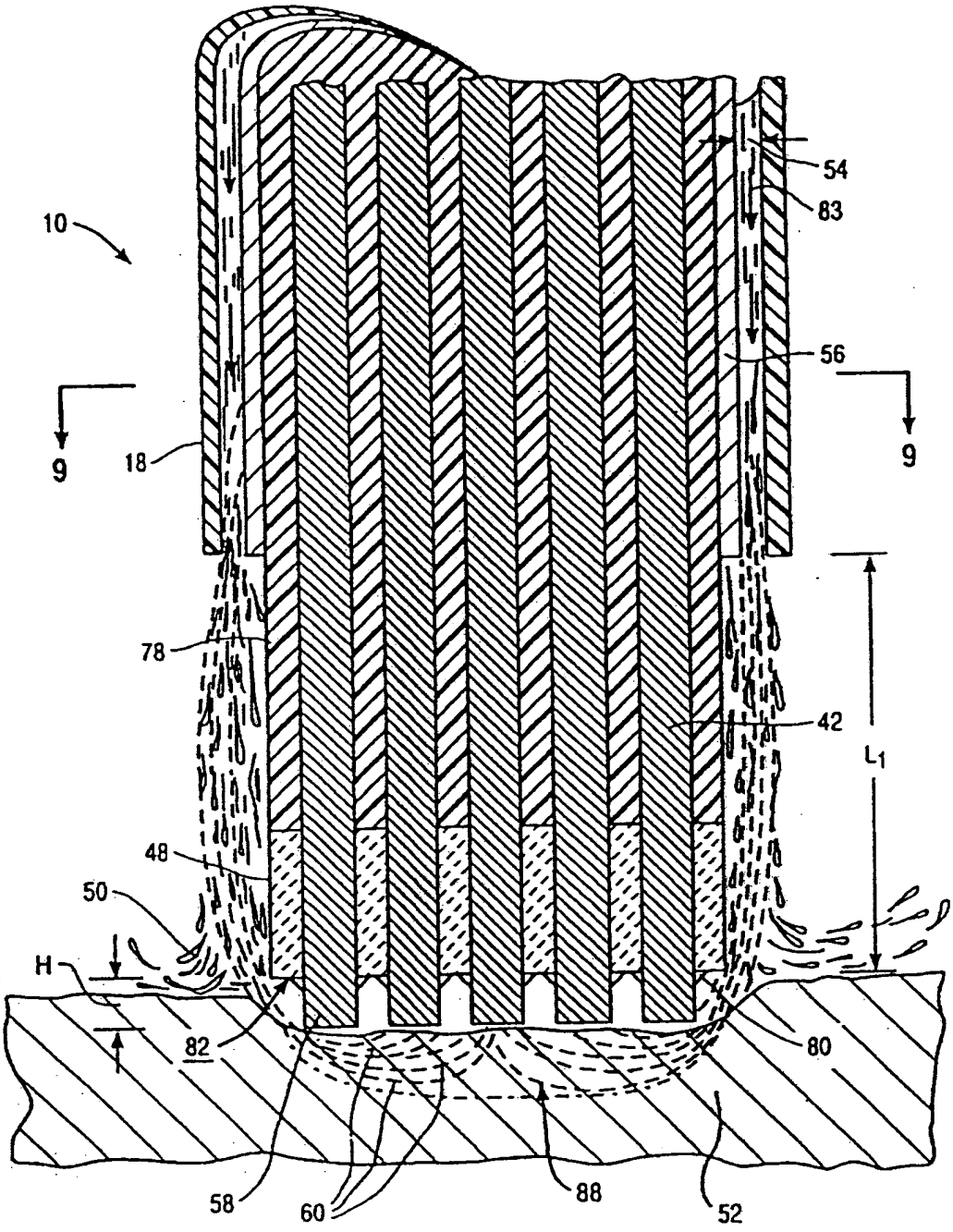

FIG. 8

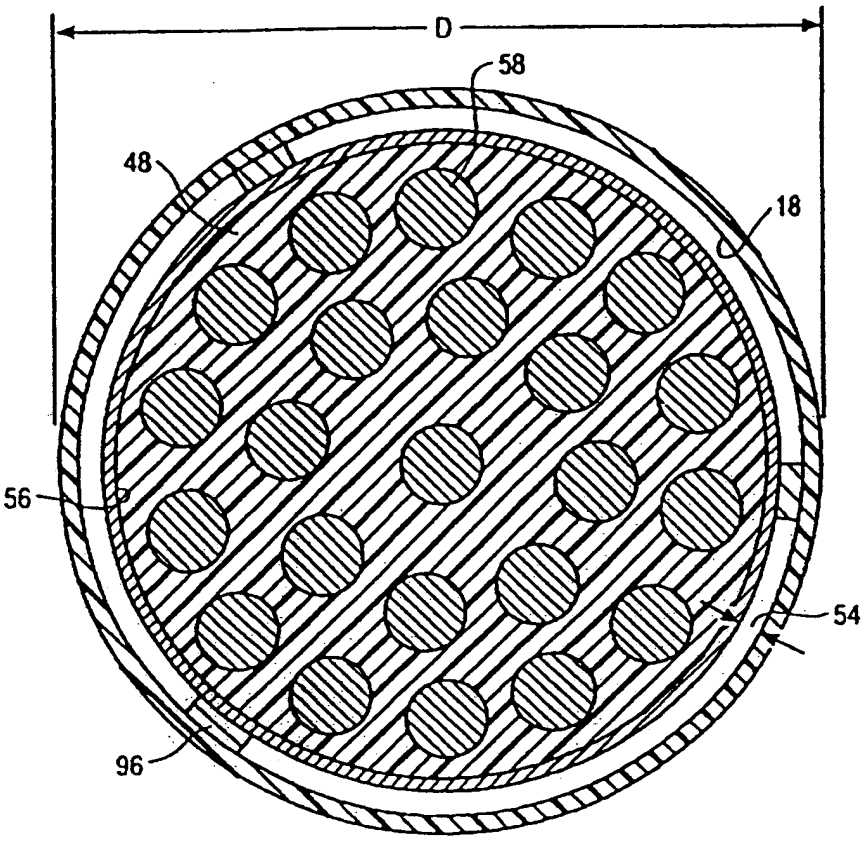

FIG. 9

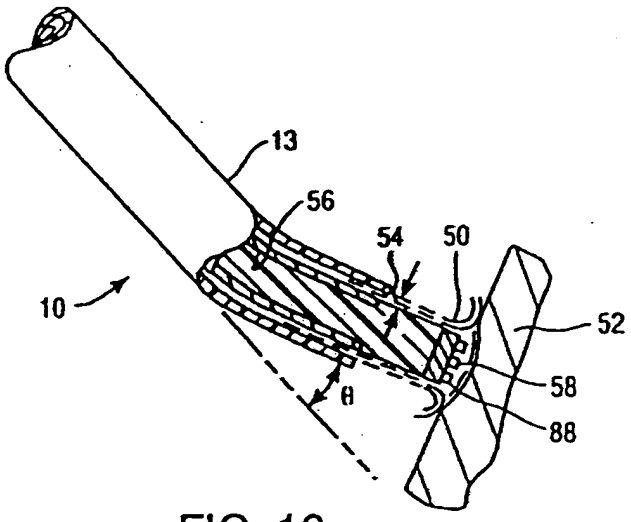

FIG. 10

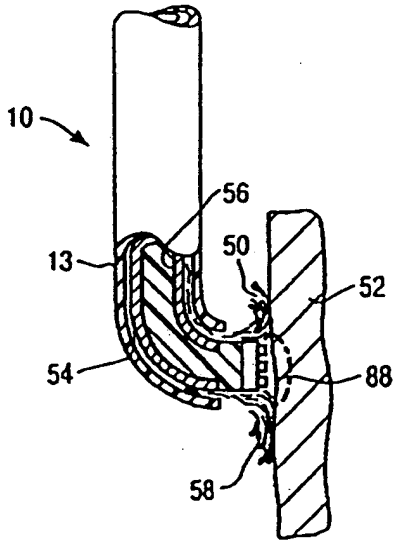

FIG. 11

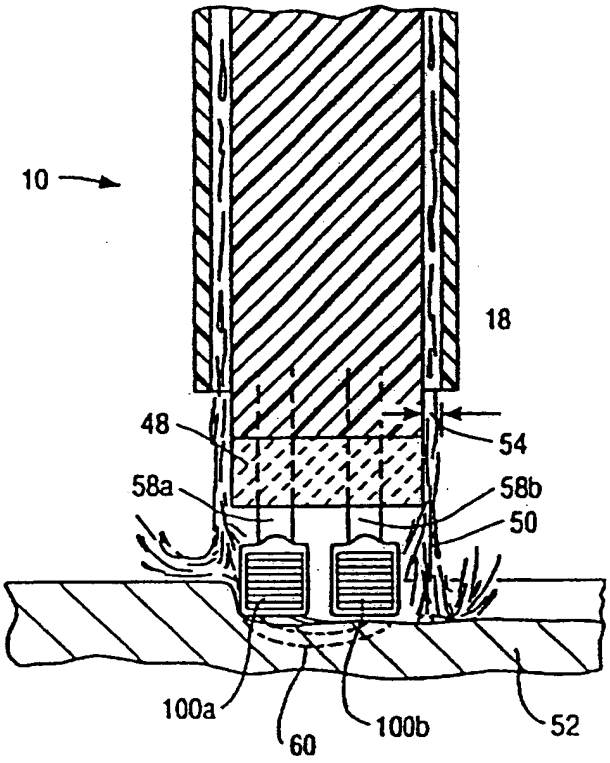

FIG. 12

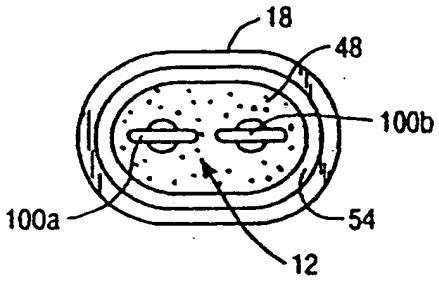

FIG. 13

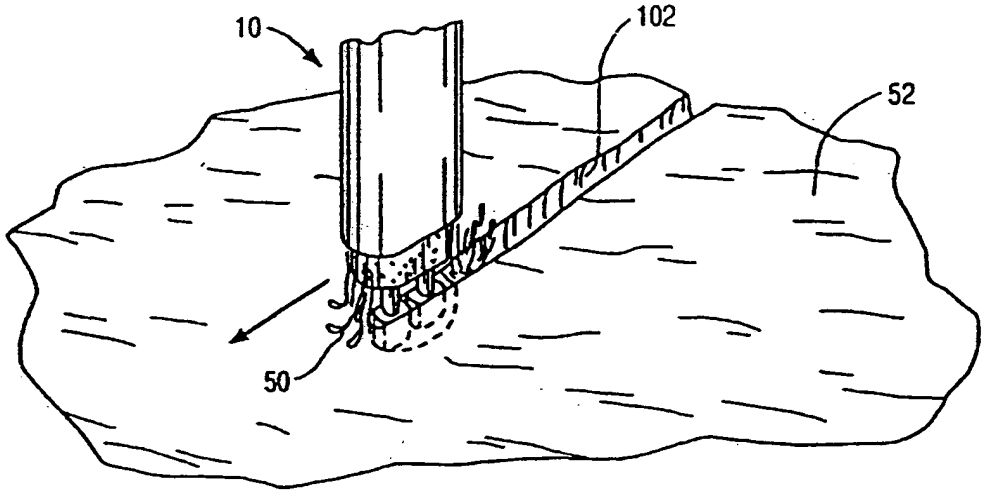

FIG. 14

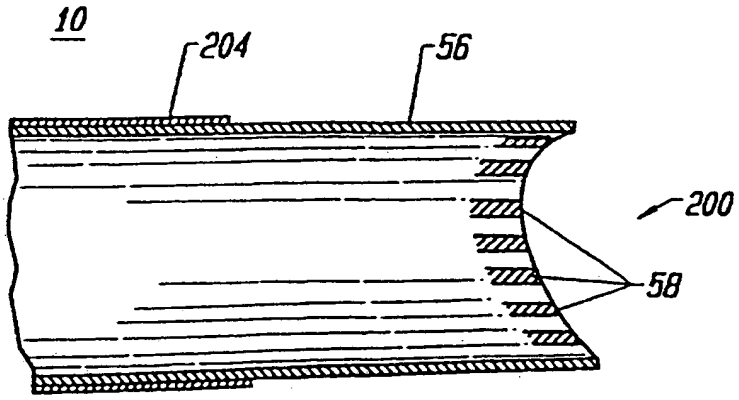

FIG. 15

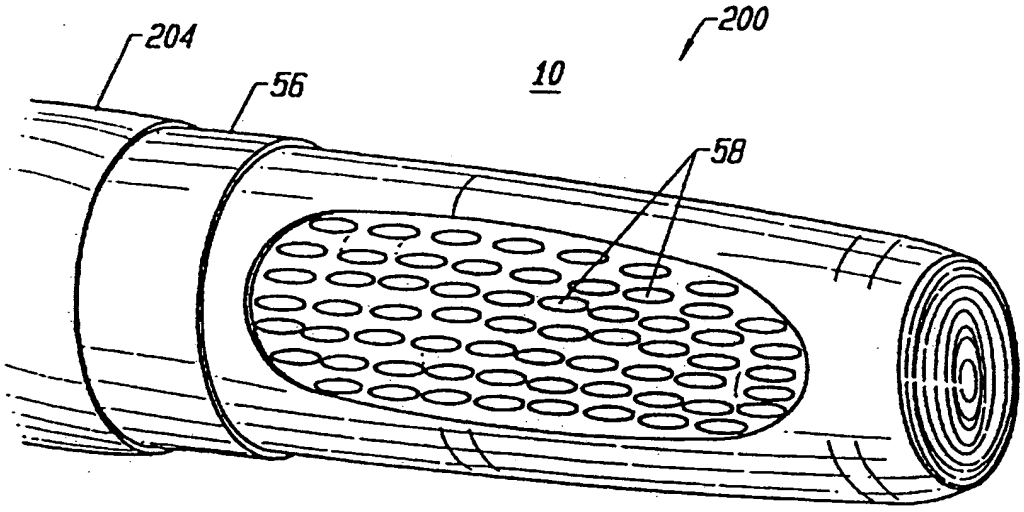

FIG. 16

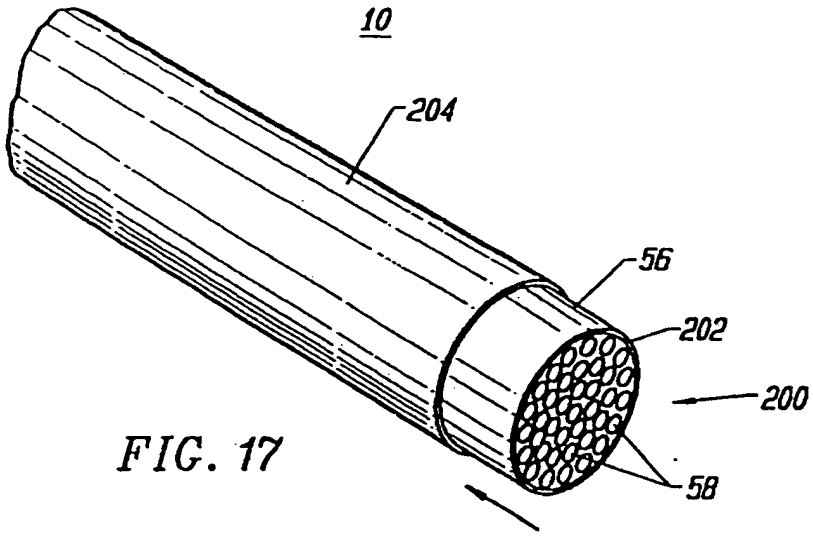

FIG. 17

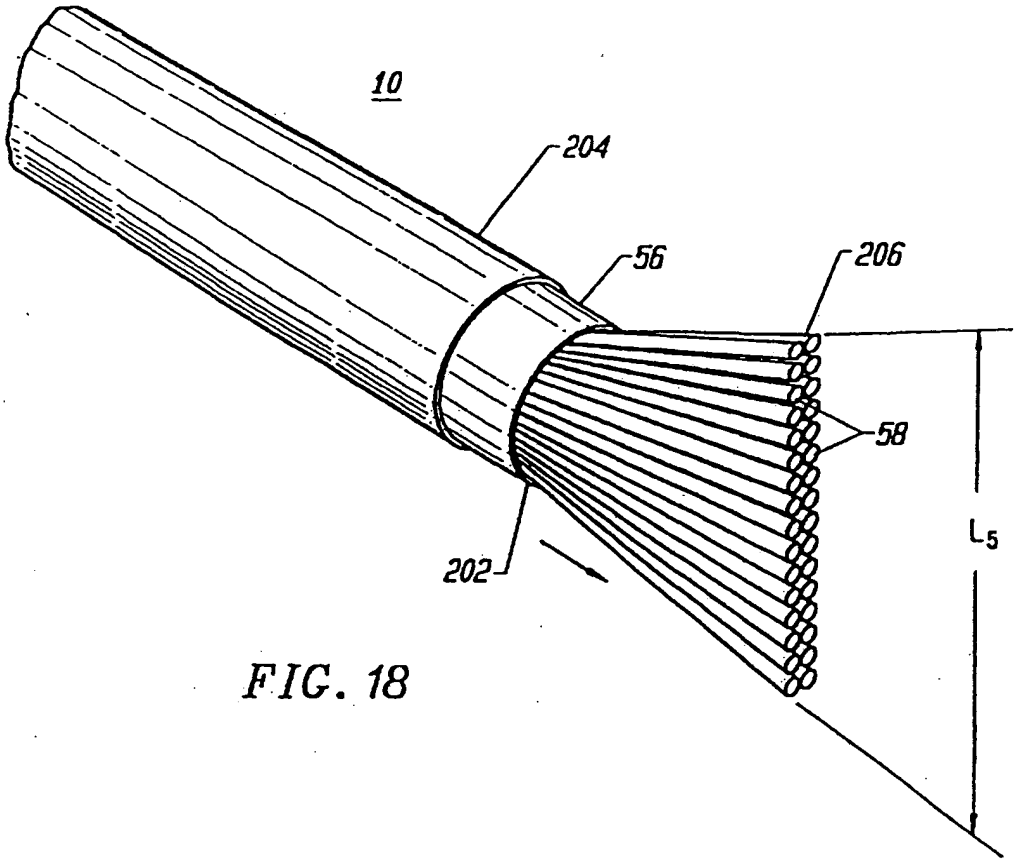

FIG. 18

SYSTEM AND METHOD FOR ELECTROSURGICAL CUTTING AND ABLATION

BACKGROUND OF THE INVENTION

This is a Division of application Ser. No. 08/485,219 filed Jun. 7, 1995 pending, which is a continuation-in-part of application Ser No. 08/446,767 filed on Jun. 2, 1995 and pending; which was a continuation-in-part of application Ser. No. 08/059,681, filed on May 10, 1993, now abandoned; which was a continuation-in-part of application Ser. No. 07/958,977, filed on Oct. 9, 1992, now U.S. Pat. No. 5,366,443; which was a continuation-in-part of application Ser. No. 07/817,575, filed on Jan. 7, 1992, now abandoned; the full disclosures of which are incorporated herein by reference.

1. Field of the Invention

The present invention relates generally to the field of electrosurgery and, more particularly, to surgical devices and methods which employ high frequency voltage to cut and ablate tissue.

The field of electrosurgery includes a number of loosely related surgical techniques which have in common the application of electrical energy to modify the structure or integrity of patient tissue. Electrosurgical procedures usually operate through the application of very high frequency currents to cut or ablate tissue structures, where the operation can be monopolar or bipolar. Monopolar techniques rely on external grounding of the patient, where the surgical device defines only a single electrode pole. Bipolar devices comprise both electrodes for the application of current between their surfaces.

Electrosurgical procedures and techniques are particularly advantageous since they generally reduce patient bleeding and trauma associated with cutting operations. Additionally, electrosurgical ablation procedures, where tissue surfaces and volume may be reshaped, cannot be duplicated through other treatment modalities.

Current electrosurgical devices and procedures, however, suffer from a number of disadvantages. For example, monopolar devices generally direct electric current along a defined path from the exposed or active electrode through the patient's body to the return electrode, which is externally attached to a suitable location on the patient. This creates the potential danger that the electric current will flow through undefined paths in the patient's body, thereby increasing the risk of unwanted electrical stimulation to portions of the patient's body. In addition, since the defined path through the patient's body has a relatively high impedance (because of the large distance or resistivity of the patient's body), large voltage differences must typically be applied between the return and active electrodes in order to generate a current suitable for ablation or cutting of the target tissue. This current, however, may inadvertently flow along body paths having less impedance than the defined electrical path, which will substantially increase the current flowing through these paths, possibly causing damage to or destroying surrounding tissue.

Bipolar electrosurgical devices have an inherent advantage over monopolar devices because the return current path does not flow through the patient. In bipolar electrosurgical devices, both the active and return electrode are typically exposed so that they may both contact tissue, thereby providing a return current path from the active to the return electrode through the tissue. One drawback with this configuration, however, is that the return electrode may

cause tissue desiccation or destruction at its contact point with the patient's tissue. In addition, the active and return electrodes are typically positioned close together to ensure that the return current flows directly from the active to the return electrode. The close proximity of these electrodes generates the danger that the current will short across the electrodes, possibly impairing the electrical control system and/or damaging or destroying surrounding tissue.

The use of electrosurgical procedures (both monopolar and bipolar) in electrically conductive environments can be further problematic. For example, many arthroscopic procedures require flushing of the region to be treated with isotonic saline (also referred to as normal saline), both to maintain an isotonic environment and to keep the field of viewing clear. The presence of saline, which is a highly conductive electrolyte, can also cause shorting of the electrosurgical electrode in both monopolar and bipolar modes. Such shorting causes unnecessary heating in the treatment environment and can further cause non-specific tissue destruction.

In response to the various problems associated with electrosurgical procedures in electrically conductive environments, new methods and devices have been developed by the applicant. These methods and devices provide selective power delivery to the target tissue while minimizing power delivery to the surrounding electrically conductive irrigant. These methods are particularly useful in isotonic saline filled body cavities, such as arthroscopic, urologic or gynecologic cavities. The irrigant flooded body cavity provides good visibility, facilitates the removal of bubbles or other debris, minimizes the possibility of air embolism and protects certain tissue from dehydration. Such methods and devices are more fully described in previously filed, commonly assigned applications Ser. Nos. 08/059,681, 07/958,977 and 07/817,575, the full disclosures of which have been incorporated by reference.

Many surgical procedures, such as oral, laparoscopic and open surgical procedures, are not performed with the target tissue submerged under an irrigant. In laparoscopic procedures, such as the resection of the gall bladder from the liver, for example, the abdominal cavity is pressurized with carbon dioxide (pneumoperitoneum) to provide working space for the instruments and to improve the surgeon's visibility of the surgical site. Other procedures, such as the ablation of muscle or gingiva tissue in the mouth or the ablation and necrosis of diseased tissue, are also typically performed in a "dry" environment or field (i.e., not submerged under an electrically conducting irrigant).

For these and other reasons, improved systems and methods are desired for the electrosurgical ablation and cutting of tissue. These systems and methods should be capable of providing a direct return current path from the active electrode, through the target site, to the return electrode to minimize the dangers of electrical current flowing through undefined paths in the patient's body. The system should also be configured to minimize contact between the return electrode and surrounding tissue and to avoid current shorting between the active and return electrodes. Preferably, the system will be configured to apply high frequency voltage for the cutting and ablation of tissue in relatively dry environments, such as those encountered in oral, laparoscopic and open surgical procedures.

2. Description of the Background Art

Devices incorporating radio frequency electrodes for use in electrosurgical and electrocautery techniques are described in Rand et al. (1985) *J. Arthro. Surg.* 1: 242–246

and U.S. Pat. Nos. 5,281,216; 4,943,290; 4,936,301; 4,593,691; 4,228,800; and 4,202,337. U.S. Pat. Nos. 4,943,290 and 4,036,301 describe methods for injecting non-conducting liquid over the tip of a monopolar electrosurgical electrode to electrically isolate the electrode, while energized, from a surrounding electrically conducting irrigant. U.S. Pat. Nos. 5,195,959 and 4,674,499 describe monopolar and bipolar electrosurgical devices, respectively, that include a conduit for irrigating the surgical site.

SUMMARY OF THE INVENTION

The present invention provides an apparatus and method for selectively applying electrical energy to structures within a patient's body. The apparatus and method allow the surgical team to perform electrosurgical interventions, such as ablation and cutting of body structures, without requiring the tissue to be submerged in an electrically conducting irrigant, such as isotonic saline. The apparatus and method of the present invention are particularly useful for treating and shaping gingiva, for tissue dissection, e.g. separation of gall bladder from the liver, and ablation and necrosis of diseased tissue, such as tumors.

The method of the present invention comprises positioning an electrosurgical probe adjacent the target tissue so that at least one active electrode is brought into at least partial contact or close proximity with the target site. Electrically conducting liquid, such as isotonic saline, is directed through a fluid path past a return electrode and to the target site to generate a current flow path between the target site and the return electrode. High frequency voltage is then applied between the active and return electrode through the current flow path created by the electrically conducting liquid in either a bipolar or monopolar manner. The probe may then be translated, reciprocated or otherwise manipulated to cut the tissue or effect the desired depth of ablation.

The above described method is particularly effective in a dry environment (i.e., the tissue is not submerged in fluid), such as open, laparoscopic or oral surgery, because the electrically conducting liquid provides a suitable current flow path from the target site to the return electrode. The active electrode is preferably disposed at the distal end of the probe and the return electrode is spaced from the active electrode and enclosed within an insulating sheath. This minimizes exposure of the return electrode to surrounding tissue and minimizes possible shorting of the current between the active and return electrodes. In oral procedures, the probe may be introduced directly into the cavity of the open mouth so that the active electrode is positioned against gingival or mucosal tissue. In laparoscopic procedures, the probe will typically be passed through a conventional trocar cannula while viewing of the operative site is provided through the use of a laparoscope disposed in a separate cannula.

The apparatus according to the present invention comprises an electrosurgical probe having a shaft with a proximal end, a distal end, and at least one active electrode at or near the distal end. A connector is provided at or near the proximal end of the shaft for electrically coupling the active electrode to a high frequency voltage source. A return electrode coupled to the voltage source is spaced a sufficient distance from the active electrode to substantially avoid or minimize current shorting therebetween and to shield the return electrode from tissue. The return electrode may be provided integral with the shaft of the probe or it may be separate from the shaft (e.g., on a liquid supply instrument). In both cases, the return electrode defines an inner passage

for flow of electrically conducting liquid therethrough. The liquid is directed through the return electrode and over the active electrode to thereby provide a return current flow path between the tissue target site and the return electrode.

In a preferred aspect of the invention, the active electrode comprises an electrode array having a plurality of electrically isolated electrode terminals disposed over a contact surface, which may be a planar or non-planar surface and which may be located at the distal tip or over a lateral surface of the shaft, or over both the tip and lateral surface(s). The electrode array will include at least two and preferably more electrode terminals, and may further comprise a temperature sensor. In a preferred aspect, each electrode terminal will be connected to the proximal connector by an electrically isolated conductor disposed within the shaft. The conductors permit independent electrical coupling of the electrode terminals to a high frequency power supply and control system with optional temperature monitor for operation of the probe. The control system preferably incorporate active and/or passive current limiting structures, which are designed to limit current flow when the associated electrode terminal is in contact with a low resistance return path back to the return electrode.

The use of such electrode arrays in electrosurgical procedures is particularly advantageous as it has been found to limit the depth of tissue necrosis without substantially reducing power delivery and ablation rates. The voltage applied to each electrode terminal causes electrical energy to be imparted to any body structure which is contacted by, or comes into close proximity with, the electrode terminal, where a current flow through all low electrical impedance paths is preferably but not necessarily limited. It will be appreciated that such low impedance paths generally occur when an electrode terminal does not contact or come into close proximity with the body structure, but rather is in contact with a low impedance environment, such as the saline, or other electrolyte being introduced past the return electrode. The presence of an electrolyte provides a relatively low impedance path back to the common or return electrode.

The apparatus and method of the present invention provide a number of advantages, particularly in respect to the ablation or cutting of tissue. The ability to control current flow through individual electrode terminals minimizes power dissipation into the surrounding medium. Limited power dissipation, in turn, permits the use of electrolytic irrigants, such as isotonic saline, to create a current flow path between the active electrode terminals and the return electrode. The isotonic saline may also be used to simultaneously irrigate the surgical site, which provides a number of well known physiological advantages. In addition, the ability to operate in a bipolar or quasi-bipolar mode reduces the risk of unwanted electrical stimulation from return current flowing through the patient's body, which can cause muscle spasms and can limit the depth of tissue necrosis during ablative resection.

A further understanding of the nature and advantages of the invention will become apparent by reference to the remaining portions of the specification and drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of the electrosurgical system including an electrosurgical probe, an electrically conducting liquid supply and an electrosurgical power supply constructed in accordance with the principles of the present invention;

FIG. 2A is an enlarged, cross-sectional view of the distal tip of the electrosurgical probe of FIG. 1 illustrating an electrode arrangement suitable for rapid cutting and ablation of tissue structures;

FIG. 2B is an enlarged end view of the distal tip of the electrosurgical probe of FIG. 1;

FIG. 2C is a cross-sectional view of the proximal end of the electrosurgical probe, illustrating an arrangement for coupling the probe to the electrically conducting liquid supply of FIG. 1;

FIG. 3 is a detailed cross-sectional view of an alternative embodiment of the electrosurgical probe of FIG. 1;

FIG. 4 is an end view of the distal end of the electrosurgical probe of FIG. 3;

FIG. 5 is an end view of an another embodiment of the electrosurgical probe of FIG. 1;

FIG. 6 is a partial cross-sectional side view of a further embodiment of the electrosurgical probe with the electrode array disposed transversely to the axis of the probe;

FIG. 7 is a partial front cross-sectional view of an electrosurgical probe and an electrically conductive liquid supply shaft illustrating use of the probe and the shaft in ablating target tissue;

FIG. 8 is an enlarged, cross-sectional view of the distal tip of yet another embodiment of the electrosurgical probe of FIG. 1;

FIG. 9 is a detailed end view of the probe of FIG. 8;

FIG. 10 is a side view of an electrosurgical probe having a shaft with an angled distal portion;

FIG. 11 is a side view of an electrosurgical probe having a shaft with a perpendicular distal portion;

FIG. 12 is a schematic view of an electrosurgical probe having two screwdriver-shaped electrodes extending from the distal end;

FIG. 13 is an end view of the probe of FIG. 12; and

FIG. 14 illustrates use of the probe of FIG. 12 for the rapid cutting of tissue.

FIG. 15 illustrates another alternative electrode surface configuration for the electrosurgical probe of FIG. 1.

FIG. 16 illustrates a second alternative electrode surface configuration.

FIGS. 17 and 18 illustrate an electrosurgical probe having an electrode surface which can be transformed from a flat, circular array (FIG. 17) to an elongate, linear array (FIG. 18) suitable for use in surgical cutting.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention provides an apparatus and method for selectively applying electrical energy to a target location within a patient's body, such as solid tissue or the like, particularly including gingival tissues and mucosal tissues located in the mouth. In addition, tissues which may be treated by the system and method of the present invention include tumors, abnormal tissues, and the like. For convenience, the remaining disclosure will be directed specifically to the cutting, shaping or ablation of gingival or mucosal tissue in oral surgical procedures, but it will be appreciated that the system and method can be applied equally well to procedures involving other tissues of the body, as well as to other procedures including open surgery, laparoscopic surgery, thoracoscopic surgery, and other endoscopic surgical procedures.

The present invention uses an electrode array including a plurality of independently current-limited and/or power-

controlled electrode terminals distributed over a distal contact surface of a probe to apply electrical energy selectively to the target tissue while limiting the unwanted application of electrical energy to the surrounding tissue and environment resulting from power dissipation into surrounding electrically conductive liquids, such as blood, normal saline, and the like.

The electrosurgical probe will comprise a shaft having a proximal end and a distal end which supports an electrode array near its distal end. The shaft may assume a wide variety of configurations, with the primary purpose being to mechanically support the electrode array and permit the treating physician to manipulate the array from a proximal end of the shaft. Usually, the shaft will be a narrow-diameter rod or tube, more usually having dimensions which permit it to be introduced into a body cavity, such as the mouth or the abdominal cavity, through an associated trocar or cannula in a minimally invasive procedure, such as arthroscopic, laparoscopic, thoracoscopic, and other endoscopic procedures. Thus, the shaft will typically have a length of at least 5 cm for oral procedures and at least 10 cm, more typically being 20 cm, or longer for endoscopic procedures. The shaft will typically have a diameter of at least 1 mm and frequently in the range from 1 to 10 mm. The shaft may be rigid or flexible, with flexible shafts optionally being combined with a generally rigid external tube for mechanical support. Flexible shafts may be combined with pull wires, shape memory actuators, and other known mechanisms for effecting selective deflection of the distal end of the shaft to facilitate positioning of the electrode array. The shaft will usually include a plurality of wires or other conductive elements running axially therethrough to permit connection of the electrode array to a connector at the proximal end of the shaft. Specific shaft designs will be described in detail in connection with the figures hereinafter.

The circumscribed area of the electrode array is in the range from 0.25 mm^2 to 75 mm^2, preferably from 0.5 mm^2 to 40 mm^2, and will usually include at least two isolated electrode terminals, more usually at least four electrode terminals, preferably at least six electrode terminals, and often 50 or more electrode terminals, disposed over the distal contact surfaces on the shaft. By bringing the electrode array(s) on the contact surface(s) against or in close proximity with the target tissue and applying high frequency voltage between the array(s) and an additional common or return electrode in direct or indirect contact with the patient's body, the target tissue is selectively ablated or cut, permitting selective removal of portions of the target tissue while desirably minimizing the depth of necrosis to surrounding tissue. In particular, this invention provides a method and apparatus for effectively ablating and cutting tissue which may be located in close proximity to other critical organs, vessels or structures (e.g., teeth, bone) by simultaneously (1) causing electrically conducting liquid to flow between the common and active electrodes, (2) applying electrical energy to the target tissue surrounding and immediately adjacent to the tip of the probe, (3) bringing the active electrode(s) in contact or close proximity with the target tissue using the probe itself, and (4) optionally moving the electrode array axially and/or transversely over the tissue.

Each individual electrode terminal in the electrode array is electrically insulated from all other electrode terminals in the array within said probe and is connected to a power source which is isolated from each of the other electrodes in the array or to circuitry which limits or interrupts current flow to the electrode when low resistivity material (e.g.,

blood or electrically conductive saline irrigant) causes a lower impedance path between the common electrode and the individual electrode terminal. The isolated power sources for each individual electrode may be separate power supply circuits having internal impedance characteristics which limit power to the associated electrode terminal when a low impedance return path is encountered, may be a single power source which is connected to each of the electrodes through independently actuatable switches or may be provided by independent current limiting elements, such as inductors, capacitors, resistors and/or combinations thereof.

The tip region of the probe is thus composed of many independent electrode terminals designed to deliver electrical energy in the vicinity of the tip. The selective application of electrical energy to of the target tissue is achieved by connecting each individual electrode terminal and the common electrode to a power source having independently controlled or current limited channels. The common electrode may be a tubular member of conductive material proximal to the electrode array at the tip which also serves as a conduit for the supply of the electrically conducting liquid between the active and common electrodes. The application of high frequency voltage between the common electrode and the electrode array results in the generation of high electric field intensities at the distal tips of the electrodes with conduction of high frequency current from each individual electrode terminal to the said common electrode. The current flow from each individual electrode terminal to the common electrode is controlled by either active or passive means, or a combination thereof, to deliver electrical energy to the target tissue while minimizing energy delivery to surrounding (non-target) tissue and any conductive fluids which may be present (e.g., blood, electrolytic irrigants such as saline, and the like).

In a preferred aspect, this invention takes advantage of the differences in electrical resistivity between the target tissue (e.g., gingiva, muscle, fascia, tumor or other connective tissue) and the surrounding conductive liquid (e.g., isotonic saline irrigant). By way of example, for any selected level of applied voltage, if the electrical conduction path between the common electrode and one of the individual electrode terminals within the electrode array is isotonic saline irrigant liquid (having a relatively low electrical impedance), the current control means connected to the individual electrode will limit current flow so that the heating of intervening conductive liquid is minimized. On the other hand, if a portion of or all of the electrical conduction path between the common electrode and one of the individual electrode terminals within the electrode array is gingival tissue (having a relatively higher electrical impedance), the current control circuitry or switch connected to the individual electrode will allow current flow sufficient for the deposition of electrical energy and associated ablation or electrical breakdown of the target tissue in the immediate vicinity of the electrode surface.

The application of a high frequency voltage between the common or return electrode and the electrode array for appropriate time intervals effects ablation, cutting or reshaping of the target tissue. The tissue volume over which energy is dissipated (i.e., a high voltage gradient exists) may be precisely controlled, for example, by the use of a multiplicity of small electrodes whose effective diameters range from about 2 mm to 0.01 mm, preferably from about 1 mm to 0.05 mm, and more preferably from about 0.5 mm to 0.1 mm. Electrode areas for both circular and non-circular terminals will have a contact area (per electrode) below 5 mm^2, preferably being in the range from 0.0001 mm^2 to 1 mm^2.

and more preferably from 0.005 mm^2 to 0.5 mm^2. The use of small diameter electrode terminals increases the electric field intensity and reduces the extent or depth of tissue necrosis as a consequence of the divergence of current flux lines which emanate from the exposed surface of each electrode terminal. Energy deposition in tissue sufficient for irreversible damage (i.e., necrosis) has been found to be limited to a distance of about one-half to one electrode diameter. This is a particular advantage over prior electrosurgical probes employing single and/or larger electrodes where the depth of tissue necrosis may not be sufficiently limited.

In previous electrosurgical devices, increased power application and ablation rates have been achieved by increasing the electrode area. Surprisingly, with the present invention, it has been found that the total electrode area can be increased (to increase power delivery and ablation rate) without increasing the depth of necrosis by providing multiple small electrode terminals. Preferably, the terminals will be spaced-apart by a distance in the range from about one-half diameter to one diameter for optimum power delivery, as discussed below. The depth of necrosis may be further controlled by switching the applied voltage off and on to produce pulses of current, the pulses being of sufficient duration and associated energy density to effect ablation and/or cutting while being turned off for periods sufficiently long to allow for thermal relaxation between energy pulses. In this manner, the energy pulse duration and magnitude and the time interval between energy pulses are selected to achieve efficient rates of tissue ablation or cutting while allowing the temperature of the treated zone of tissue to "relax" or return to normal physiologic temperatures (usually to within 10° C. of normal body temperature [37° C.], preferably to within 5° C.) before the onset of the next energy (current) pulse.

The rate of energy delivery to the target tissue is controlled by the applied voltage level and duty cycle of the voltage pulse. The use of high frequency current minimizes induced stimulation of muscle tissue or nerve tissue in the vicinity of the body structure being treated. In addition, high frequencies minimize the risk of interfering with the natural pacing of the heart in circumstances where the probe of the present invention is used near the heart.

The power applied to the common electrode and the electrode array will be at high or radio frequency, typically between about 20 kHz and 20 MHz, usually being between about 30 kHz and 2 MHz, and preferably being between about 50 kHz and 400 kHz. The RMS (root mean square) voltage applied will usually be in the range from about 5 volts to 1000 volts, preferably being in the range from about 50 volts to 800 volts, and more preferably being in the range from about 10 volts to 500 volts. Usually, the current level will be selectively limited or controlled and the voltage applied will be independently adjustable, frequently in response to the resistance of tissues and/or fluids in the pathway between an individual electrode and the common electrode. Also, the applied current level may be in response to a temperature control means which maintains the target tissue temperature with desired limits at the interface between the electrode arrays and the target tissue. The desired surface temperature along a propagating surface just beyond the region of ablation will usually be in the range from about 40° C. to 100° C., and more usually from about 50° C. to 60° C. The tissue being ablated immediately adjacent the electrode array may reach even higher temperatures.

The preferred power source of the present invention delivers a high frequency current selectable to generate

average power levels ranging from tens of milliwatts to tens of watts per electrode, depending on the target tissue being ablated, the rate of ablation desired or the maximum allowed temperature selected for the probe tip. The power source allows the user to select the current level according to the specific requirements of a particular oral surgery, open surgery or other endoscopic surgery procedure.

The power source will be current limited or otherwise controlled so that undesired heating of electrically conductive fluids or other low electrical resistance media does not occur. In a presently preferred embodiment of the present invention, current limiting inductors are placed in series with each independent electrode terminal, where the inductance of the inductor is in the range of 20 uH to 5000 uH, depending on the electrical properties of the target tissue, the desired ablation rate and the operating frequency. Alternatively, capacitor-inductor (LC) circuit structures may be employed, as described previously in co-pending PCT application No. PCT/US94/05168, which has already been incorporated herein by reference. Additionally, current limiting resistors may be selected having a large positive temperature coefficient of resistance so that, as the current level begins to rise for any individual electrode in contact with a low resistance medium (e.g., saline irrigant), the resistance of the current limiting resistor increases significantly, thereby minimizing the power delivery from said electrode into the low resistance medium (e.g., saline irrigant).

As an alternative to such passive circuit structures, regulated current flow to each electrode terminal may be provided by a multi-channel power supply. A substantially constant current level for each individual electrode terminal within a range which will limit power delivery through a low resistance path, e.g., isotonic saline irrigant, would be selected by the user to achieve the desired rate of cutting or ablation. Such a multi-channel power supply thus provides a substantially constant current source with selectable current level in series with each electrode terminal, wherein all electrodes will operate at or below the same, user selectable maximum current level. Current flow to all electrode terminals could be periodically sensed and stopped if the temperature measured at the surface of the electrode array exceeds user selected limits. Particular control system designs for implementing this strategy are well within the skill of the art.

Yet another alternative involves the use of one or several power supplies which allow one or several electrodes to be simultaneously energized and which include active control means for limiting current levels below a preselected maximum level. In this arrangement, only one or several electrodes would be simultaneously energized for a brief period. Switching means would allow the next one or several electrodes to be energized for a brief period. By sequentially energizing one or several electrodes, the interaction between adjacent electrodes can be minimized (for the case of energizing several electrode positioned at the maximum possible spacing within the overall envelope of the electrode array) or eliminated (for the case of energizing only a single electrode at any one time). As before, a resistance measurement means may be employed for each electrode prior to the application of power wherein a (measured) low resistance (below some preselected level) will prevent that electrode from being energized during given cycle. By way of example, the sequential powering and control scheme of the present invention would function in a manner similar to an automobile distributor. In this example, an electrical contact rotates past terminals connected to each spark plug. In this

example, each spark plug corresponds to the exposed surface of each of the electrodes. In addition, the present invention includes the means to measure the resistance of the medium in contact with each electrode and cause voltage to be applied only if the resistance exceeds a preselected level.

The electrode array is formed over a contact surface on the shaft of the electrosurgical probe. The common (return) electrode surface will be recessed relative to the distal end of the probe and may be recessed within the conduit provided for the introduction of electrically conducting liquid to the site of the target tissue and array of active electrodes. In the exemplary embodiment, the shaft will be cylindrical over most of its length, with the contact surface being formed at the distal end of the shaft. In the case of laparoscopic or endoscopic applications, the contact surface may be recessed since it helps protect and shield the electrode terminals on the surface while they are being introduced, particularly while being introduced through the working channel of a trocar channel or a viewing scope.

The area of the contact surface can vary widely, and the contact surface can assume a variety of geometries, with particular areas in geometries being selected for specific applications. Electrode array contact surfaces can have areas in the range from 0.25 mm^2 to 50 mm^2, usually being from 1 mm^2 to 20 mm^2. The geometries can be planar, concave, convex, hemispherical, conical, or virtually any other regular or irregular shape. Most commonly, the electrode arrays will be formed at the distal tip of the electrosurgical probe shaft, frequently being planar, disk-shaped, or hemispherical surfaces for use in reshaping procedures or being linear arrays for use in cutting. Alternatively or additionally, the electrode arrays may be formed on lateral surfaces of the electrosurgical probe shaft (e.g., in the manner of a spatula), facilitating access to certain body structures in electrosurgical procedures.

Referring to the drawings in detail, wherein like numerals indicate like elements, an electrosurgical system 11 is shown constructed according to the principles of the present invention. Electrosurgical system 11 generally comprises an electrosurgical probe 10 connected to a power supply 28 for providing high frequency voltage to a target tissue 52 and a liquid source 21 for supplying electrically conducting fluid 50 to probe 10.

In an exemplary embodiment as shown in FIG. 1, electrosurgical probe 10 includes an elongated shaft 13 which may be flexible or rigid, with flexible shafts optionally including support cannulas or other structures (not shown). Probe 10 includes a connector 19 at its proximal end and an array 12 of electrode terminals 58 disposed on the distal tip of shaft 13. A connecting cable 34 has a handle 22 with a connector 20 which can be removably connected to connector 19 of probe 10. The proximal portion of cable 34 has a connector 26 to couple probe 10 to power supply 28. The electrode terminals 58 are electrically isolated from each other and each of the terminals 58 is connected to an active or passive control network within power supply 28 by means of a plurality of individually insulated conductors 42 (see FIG. 2C). Power supply 28 has a selection means 30 to change the applied voltage level. Power supply 28 also includes means for energizing the electrodes 58 of probe 10 through the depression of a pedal 39 in a foot pedal 37 positioned close to the user. The foot pedal 37 may also include a second pedal (not shown) for remotely adjusting the energy level applied to electrodes 58. The specific design of a power supply which may be used with the electrosurgical probe of the present invention is described in parent application PCT/US94/05168, the full disclosure of which has previously been incorporated herein by reference.

Referring to FIGS. 2A and 2B, the electrically isolated electrode terminals 58 are spaced-apart over an electrode array surface 82. The electrode array surface 82 and individual electrode terminals 58 will usually have dimensions within the ranges set forth above. In the preferred embodiment, the electrode array surface 82 has a circular cross-sectional shape with a diameter D (FIG. 2B) in the range from 1 mm to 10 mm. Electrode array surface 82 may also have an oval shape, having a length L in the range of 1 mm to 20 mm and a width W in the range from 0.5 mm to 7 mm, as shown in FIG. 5. The individual electrode terminals 58 will protrude over the electrode array surface 82 by a distance (H) from 0 mm to 2 mm, preferably from 0 mm to 1 mm (see FIG. 3). As described above, electrode terminals which are flush with the surface, or protrude by a minimum distance, will provide less aggressive ablation and are particularly suitable for smoothing of treated tissue surfaces and providing hemostasis to inhibit or prevent bleeding of treated surfaces.

The electrode terminals 58 are preferably composed of a refractory, electrically conductive metal or alloy, such as platinum, platinum alloys, titanium, titanium alloys and the like. Platinum is the preferred choice for electrode terminal material since it is biocompatible, has a low erosion rate, and can be readily fabricated and attached to conductors 42 within the shaft 13 of electrosurgical probe 10. As shown in FIG. 2B, the electrode terminals 58 are anchored in a support matrix 48 of suitable insulating material (e.g., ceramic or glass material, such as alumina, zirconia and the like) which could be formed at the time of manufacture in a flat, hemispherical or other shape according to the requirements of a particular procedure. The preferred support matrix material is alumina, available from Kyocera Industrial Ceramics Corporation, Elkgrove, Ill., because of its high thermal conductivity, good electrically insulative properties, high flexural modulus, resistance to carbon tracking, biocompatibility, and high melting point.

As shown in FIG. 2A, the support matrix 48 is adhesively joined to a tubular support member 78 that extends most or all of the distance between matrix 48 and the proximal end of probe 10. Tubular member 78 preferably comprises an electrically insulating material, such as an epoxy or silicone-based material. In a preferred construction technique, electrode terminals 58 extend through pre-formed openings in the support matrix 48 so that they protrude above electrode array surface 82 by the desired distance H (FIG. 3). The electrodes are then bonded to the distal surface 82 of support matrix 48, typically by an inorganic sealing material 80. Sealing material 80 is selected to provide effective electrical insulation, and good adhesion to both the alumina matrix 48 and the platinum or titanium electrode terminals. Sealing material 80 additionally should have a compatible thermal expansion coefficient and a melting point well below that of platinum or titanium and alumina or zirconia, typically being a glass or glass ceramic.

In the embodiment shown in FIGS. 2A and 2B, probe 10 includes a return electrode 56 for completing the current path between electrode terminals 58 and power supply 28. Return electrode 56 is preferably an annular member positioned around the exterior of shaft 13 of probe 10. Return electrode 56 may fully or partially circumscribe tubular support member 78 to form an annular gap 54 therebetween for flow of electrically conducting liquid 50 therethrough, as discussed below. Gap 54 preferably has a width in the range of 0.25 mm to 4 mm. Return electrode 56 extends from the proximal end of probe 10, where it is suitably connected to power supply 28 via connectors 19, 20, to a point slightly proximal of electrode array surface 82, typically about 1 mm to 10 mm.

Return electrode 56 is disposed within an electrically insulative jacket 18, which is typically formed as one or more electrically insulative sheaths or coatings, such as polytetrafluoroethylene, polyamide, and the like. The provision of the electrically insulative jacket 18 over return electrode 56 prevents direct electrical contact between return electrode 56 and any adjacent body structure. Such direct electrical contact between a body structure (e.g., tendon) and an exposed common electrode member 56 could result in unwanted heating and necrosis of the structure at the point of contact causing necrosis.

Return electrode 56 is preferably formed from an electrically conductive material, usually metal, which is selected from the group consisting of stainless steel, platinum or its alloys, titanium or its alloys, molybdenum or its alloys, and nickel or its alloys. The return electrode 56 may be composed of the same metal or alloy which forms the electrode terminals 58 to minimize any potential for corrosion or the generation of electrochemical potentials due to the presence of dissimilar metals contained within an electrically conductive fluid 50, such as isotonic saline (discussed in greater detail below).

As shown in FIG. 2A, return electrode 56 is not directly connected to electrode terminals 58. To complete this current path so that terminals 58 are electrically connected to return electrode 56 via target tissue 52, electrically conducting liquid 50 (e.g., isotonic saline) is caused to flow along liquid paths 83. Liquid paths 83 are formed by annular gap 54 between outer return electrode 56 and tubular support member 78 and an inner lumen 57 within an inner tubular member 59. The electrically conducting liquid 50 flowing through fluid paths 83 provides a pathway for electrical current flow between target tissue 52 and return electrode 56, as illustrated by the current flux lines 60 in FIG. 2A. When a voltage difference is applied between electrode array 12 and return electrode 56, high electric field intensities will be generated at the distal tips of terminals 58 with current flow from array 12 through the target tissue to the return electrode, the high electric field intensities causing ablation of tissue 52 in zone 88.

FIGS. 2C, 3 and 4 illustrate an alternative embodiment of electrosurgical probe 10 which has a return electrode 55 positioned within tubular member 78. Return electrode 55 is preferably a tubular member defining an inner lumen 57 for allowing electrically conducting liquid 50 (e.g., isotonic saline) to flow therethrough in electrical contact with return electrode 55. In this embodiment, a voltage difference is applied between electrode terminals 58 and return electrode 55 resulting in electrical current flow through the electrically conducting liquid 50 as shown by current flux lines 60 (FIG. 3). As a result of the applied voltage difference and concomitant high electric field intensities at the tips of electrode terminals 58, tissue 52 becomes ablated or transected in zone 88.

FIG. 2C illustrates the proximal or connector end 70 of probe 10 in the embodiment of FIGS. 3 and 4. Connector 19 comprises a plurality of individual connector pins 74 positioned within a housing 72 at the proximal end 70 of probe 10. Electrode terminals 58 and the attached insulating conductors 42 extend proximally to connector pins 74 in connector housing 72. Return electrode 55 extends into housing 72, where it bends radially outward to exit probe 10. As shown in FIGS. 1 and 2C, a liquid supply tube 15 removably couples liquid source 21, (e.g., a bag of fluid elevated above the surgical site or having a pumping device), with return electrode 55. Preferably, an insulating jacket 16 covers the exposed portions of electrode 55. One of the connector pins

76 is electrically connected to return electrode 55 to couple electrode 55 to power supply 28 via cable 34. A manual control valve 17 may also be provided between the proximal end of electrode 55 and supply tube 15 to allow the surgical team to regulate the flow of electrically conducting liquid 50.

FIG. 6 illustrates another embodiment of probe 10 where the distal portion of shaft 13 is bent so that electrode terminals extend transversely to the shaft. Preferably, the distal portion of shaft 13 is perpendicular to the rest of the shaft so that electrode array surface 82 is generally parallel to the shaft axis, as shown in FIG. 6. In this embodiment, return electrode 55 is mounted to the outer surface of shaft 13 and is covered with an electrically insulating jacket 18. The electrically conducting fluid 50 flows along flow path 83 through return electrode 55 and exits the distal end of electrode 55 at a point proximal of electrode surface 82. The fluid is directed exterior of shaft to electrode surface 82 to create a return current path from electrode terminals 58, through target tissue 52, to return electrode 55, as shown by current flux lines 60.

FIG. 7 illustrates another embodiment of the invention where electrosurgical system 11 further includes a liquid supply instrument 64 for supplying electrically conducting fluid 50 between electrode terminals 58 and return electrode 55. Liquid supply instrument 64 comprises an inner tubular member or return electrode 55 surrounded by an electrically insulating jacket 18. Return electrode 55 defines an inner passage 83 for flow of fluid 50. As shown in FIG. 7, the distal portion of instrument 64 is preferably bent so that liquid 50 is discharged at an angle with respect to instrument 64. This allows the surgical team to position liquid supply instrument 64 adjacent electrode surface 82 with the proximal portion of supply instrument 64 oriented at a similar angle to probe 10.

FIGS. 8 and 9 illustrate another embodiment of probe 10 where the return electrode is an outer tubular member 56 that circumscribes support member 78 and conductors 42. Insulating jacket 18 surrounds tubular member 56 and is spaced from member 56 by a plurality of longitudinal ribs 96 to define an annular gap 54 therebetween (FIG. 9). Annular gap preferably has a width in the range of 0.25 mm to 4 mm. Ribs 96 can be formed on either the jacket 18 or member 56. The distal end of return electrode 56 is a distance L_1 from electrode surface 82. Distance L_1 is preferably about 0.5 to 10 mm and more preferably about 1 to 10 mm.

As shown in FIG. 8, electrically conducting liquid 50 flows through annular gap 54 (in electrical communication with the return electrode) and is discharged through the distal end of gap 54. The liquid 50 is then directed around support member 78 to electrode terminals 58 to provide the current pathway between the electrode terminals and return electrode 56. Since return electrode 56 is proximally recessed with respect to electrode surface 82, contact between the return electrode 56 and surrounding tissue is minimized. In addition, the distance L1 between the active electrode terminals 58 and the return electrode 56 reduces the risk of current shorting therebetween.

The present invention is not limited to an electrode array disposed on a relatively planar surface at the distal tip of probe 10, as described above. Referring to FIGS. 12–14, an alternative probe 10 includes a pair of electrodes 58*a*, 58*b* mounted to the distal end of shaft 13. Electrodes 58*a*, 58*b* are electrically connected to power supply as described above and preferably have tips 100*a*, 100*b* with a screwdriver shape. The screwdriver shape provides a greater

amount of "edges" to electrodes 58*a*, 58*b*, to increase the electric field intensity and current density at the edges and thereby improve the cutting ability as well as the ability to limit bleeding from the incised tissue (i.e., hemostasis).

As shown in FIG. 12, current flows between electrode tips 100*a* and 100*b* as indicated by current flux lines 60 to heat the target tissue 52. The surgical team then moves probe 10 transversely across tissue 52 to effect an incision 102 in tissue 52, as shown in FIG. 14.

Other modifications and variations can be made to disclose embodiments without departing from the subject invention as defined in the following claims. For example, shaft 13 of probe 10 may have a variety of configurations other than the generally linear shape shown in FIGS. 1–8. For example, shaft 13 may have a distal portion that is angled, in the range of 10° to 30° (FIG. 10) or 90° (FIGS. 11 and 6), to improve access to the operative site of the tissue 52 being ablated or cut (see FIG. 10). A shaft having a 90° bend angle may be particular useful for accessing gingiva located in the back portion of the patient's mouth and a shaft having a 10° to 30° bend angle may be useful for accessing gingiva near or in the front of the patient's mouth.

Yet another configuration for tip 200 of probe 10 is shown in FIG. 15 wherein a concave or wedge-shaped arrangement of electrodes 58 is provided to facilitate good contact with target tissue which can be embraced by said concave or wedge-shaped opening. As before, the return electrode 56 may be positioned proximal to probe tip 200.

Still yet another configuration for tip 200 of probe 10 is shown in FIG. 16 wherein electrodes 58 terminate on the side of the generally tubular (e.g., cylindrical) surface proximal to the distal end of probe 10. This configuration allows the electrode array to be brought into contact with target tissue surfaces which are tangent to the tubular surface of probe 10. As before, return electrode 56 may be positioned proximal to probe tip 200.

Another configuration for tip 200 of probe 10 is shown in FIGS. 17 and 18 and features a variable tip configuration which can be adjusted during the course of use of said probe 10. By way of example, tip 200 of probe 10 can be a cylindrical array of electrodes 58 which conforms to the cylindrical geometry of a rigid support member or cannula 202. The distal end of said cannula 202 may also serve as the common electrode 56 which is insulated in regions proximal to the tip region by an electrically insulating member 204. Referring now to FIG. 18, by extending the flexible array of electrodes 58 beyond the orifice of the cannula 202, an alternative electrode configuration can be obtained. By way of example, by placing a flat yet flexible member 206 between electrodes 58 as shown in FIG. 18, the electrode array can assume a flat "blade" shape configuration made up of a multiplicity of individual electrodes 58, each electrically insulated from all other electrodes. Such a configuration change may be advantageous if, after the insertion of the probe through a circular introduction port, the user can change the shape of the electrode array to achieve a flat "blade" shaped array whose width L_3 may be substantially greater than the circular electrode array configuration shown in FIG. 17. The increased width L_3 of the electrode array in FIG. 18 will provide the means for faster cutting through the target tissue since cutting depends primarily on the major dimension of the electrode array, either the diameter of the array (as shown in FIG. 17) or the width, L_3 of the array (as shown in FIG. 18). If the array width in FIG. 18 is three times as greater as the array diameter in FIG. 17, then the rate of cutting of the target tissue can be increased by

approximately a factor of three. An additional benefit is that the depth of necrosis in tissue on either side of the cut made with the flat electrode configuration will be less than with the larger array used in a circular configuration.

What is claimed is:

1. An electrosurgical system for use with a high frequency power supply and an electrically conducting fluid supply, the system comprising:

an electrosurgical probe comprising a shaft having a proximal end and a distal end, an electrode terminal disposed near the distal end, and a connector near the proximal end of the shaft for electrically coupling the electrode terminal to the electrosurgical power supply;

a return electrode adapted to be electrically coupled to the electrosurgical power supply; and

a fluid delivery element defining a fluid path in electrical contact with the return electrode and the electrode terminal, the fluid path having an inlet adapted to be fluidly coupled to the electrically conducting fluid supply for directing fluid along the fluid path to generate a current flow path between the return electrode and the electrode terminal.

2. An electrosurgical system as in claim 1, wherein the return forms a portion of the shaft of the electrosurgical probe.

3. An electrosurgical system as in claim 2 further including an insulating member circumscribing the return electrode, the return electrode being sufficiently spaced from the electrode terminal to minimize direct contact between the return electrode and a body structure at the target site when the electrode terminal is positioned in close proximity or in partial contact with the body structure.

4. An electrosurgical system as in claim 2, wherein the return electrode is an inner tubular member and the fluid delivery element comprises an axial lumen within the return electrode, the axial lumen forming at least a portion of the fluid path and having an inlet in communication with the electrically conducting fluid supply and an outlet in fluid communication with the electrode terminal.

5. An electrosurgical system as in claim 2, wherein the return electrode is an outer tubular member, the shaft further comprising an insulating member, wherein the fluid delivery element comprises an axial passage between the insulating member and the return electrode, the axial passage forming at least a portion of the fluid path and having an inlet in communication with the electrically conducting fluid supply and an outlet in fluid and electrical communication with the electrode terminal.

6. An electrosurgical system as in claim 1 wherein the fluid delivery element comprises a fluid supply instrument separate from the electrosurgical probe, the return electrode forming a portion of the fluid supply instrument.

7. An electrosurgical system as in claim 6 wherein the return electrode is a tubular member defining an axial lumen therein, the axial lumen being electrically connected to the tubular member and having an inlet in communication with the fluid supply and an outlet for discharging the electrically conducting fluid towards the active electrode.

8. An electrosurgical system as in claim 7 wherein the fluid supply instrument comprises an electrically insulating sheath around the tubular member, the tubular member being proximally recessed from a distal end of the sheath.

9. An electrosurgical system as in claim 1 wherein the electrode terminal comprises an electrode array disposed near the distal end of the shaft, the array including a plurality of electrically isolated electrode terminals disposed over a contact surface.

10. The electrosurgical system of claim 9 further comprising a plurality of current limiting elements each coupled to one of the electrode terminals for independently controlling current flow to each of the electrode terminals to inhibit power dissipation into the medium surrounding the target site.

11. The electrosurgical system of claim 9 further comprising means for independently controlling power to the electrode terminals based on the electrical impedance between each of the electrode terminals and the return electrode.

12. The electrosurgical system of claim 9 wherein the distal surface of the array of electrode terminals is circular in shape with a diameter in the range from 1 mm to 10 mm.

13. The electrosurgical system of claim 9 wherein the shape of the distal surface of the array of electrode terminals has an effective length of 1 mm to 20 mm and an effective width of 0.5 mm to 7.0 mm.

14. The electrosurgical system of claim 1 wherein the electrode terminal comprises a single active electrode disposed near the distal end of the shaft.

15. The electrosurgical system of claim 1 wherein the target site is selected from the group consisting essentially of the abdominal cavity, thoracic cavity, knee, shoulder, hip, hand, foot, elbow, mouth, spine, ear, nose, throat, epidermis and dermis of the patient's body.

16. The electrosurgical system of claim 1 further comprising a current limiting element for controlling current flow through the electrode terminal to inhibit power dissipation into the medium surrounding the target site.

17. The electrosurgical system of claim 16 wherein the electrically conducting fluid between the electrode terminal and the return electrode has an inherent capacitance, wherein the inherent capacitance of the tissue and electrically conducting fluid between the electrode terminal and the return electrode combined with the current limiting element together form a series resonant output circuit.

18. The system of claim 17 wherein the series resonant circuit has a resonant frequency that varies with changes in the inherent capacitance between the electrode terminal and the return electrode.

19. The electrosurgical system of claim 16 wherein the current limiting element is an active current limiting element for actively limiting current to the electrode terminal based on the electrical impedance between the electrode terminal and the return electrode.

20. The electrosurgical system of claim 19 wherein the active current limiting element measures current flow for a given applied voltage.

21. The electrosurgical system of claim 19 wherein the active current limiting element comprises an impedance sensor for indicating an electrical impedance less than a threshold level.

22. The electrosurgical system of claim 16 wherein the current limiting element is a passive current limiting element selected from the group consisting essentially of inductors, capacitors, resistors and combinations thereof.

23. The electrosurgical system of claim 1 wherein the height of the most distal portion of the electrode terminal relative to the most proximal portion of the electrode terminal exposed to the electrically conducting fluid is in the range from 0 to 2 mm.

24. The electrosurgical system of claim 1 wherein the distance between the most distal portion of the return electrode and the most proximal portion of the electrode terminal is in the range from 0.5 to 10 mm.

25. The electrosurgical system of claim 1 wherein the distal surface of the electrode terminal has a shape selected

from the group consisting essentially of flat, concave, convex, hemispherical, linear (in-line), pyramidal, conical and cylindrical.

26. The electrosurgical system of claim 1 wherein the fluid delivery element further comprises a control valve positioned on the shaft of the probe for controlling flow of the electrically conducting fluid through the fluid path.

27. The electrosurgical system of claim 1 further comprising means for controlling power to the electrode terminal based on the electrical impedance between the electrode terminal and the return electrode.

28. The electrosurgical system of claim 1 further comprising an insulating matrix surrounding and supporting the electrode terminal to electrically isolate a proximal portion of the electrode terminal from the electrically conducting fluid, the insulating matrix comprising an inorganic material.

29. The electrosurgical system of claim 28 wherein the inorganic material is selected from the group consisting essentially of ceramic, glass and glass/ceramic compositions.

30. The electrosurgical system of claim 1 wherein the electrode terminal and the return electrode are configured to effect the electrical breakdown of tissue in the immediate vicinity of the electrode terminal when high frequency voltage is applied between the electrode terminal and the return electrode in the presence of electrically conducting fluid.

31. The electrosurgical system of claim 1 wherein the electrically conducting fluid is selected from the group consisting essentially of blood and electrolytic irrigants.

32. The electrosurgical system of claim 1 wherein the electrically conducting liquid comprises saline.

33. The electrosurgical system of claim 1 wherein the electrode terminal has a distal portion configured for generating high electric field intensities sufficient to cause molecular disintegration of a body structure at the target site.

34. The electrosurgical system of claim 1 further comprising a temperature sensor adjacent the electrode terminal, the temperature sensor being adapted to be electrically coupled to the high frequency voltage source such that power delivery to the electrical terminal is limited if the measured temperature exceeds a threshold value.

35. The electrosurgical system of claim 34 wherein the temperature sensor is integral with the electrode terminal.

36. The electrosurgical system of 1 wherein the distal surface of the electrode terminal is circular in shape with a diameter in the range from 1 mm to 10 mm.

37. The electrosurgical system of claim 1 wherein the shape of the distal surface of the electrode terminal has an effective length of 1 mm to 20 mm and an effective width of 0.5 mm to 7.0 mm.

38. The system of claim 1 wherein the electrode terminal is configured for the cutting of tissue.

39. The system of claim 1 wherein the probe comprises a concave-shaped portion, the electrode terminal being disposed within the concave-shaped portion such that the concave-shaped portion at least partially surrounds the target site when the electrode terminal is brought into at least partial contact or close proximity with the target site.

40. The system of claim 1 wherein the probe comprises a lateral surface, the electrode terminal being positioned on the lateral surface such that the electrode terminal may be brought into at least partial contact or close proximity with the tissue surfaces which are substantially tangent to the electrosurgical probe.

41. The system of claim 1 wherein the electrode terminal and the return electrode are configured, upon the application

of sufficient voltage therebetween, to effect the ablation of tissue adjacent the electrode terminal such that a portion of said tissue is volumetrically removed.

42. The system of claim 1 wherein the electrode terminal is disposed at the distal tip of the electrosurgical probe.

43. The system of claim 42 wherein the return electrode is disposed proximally of the electrode terminal on the electrosurgical probe.

44. The system of claim 1 wherein the electrode terminal is a flexible electrode terminal disposed at the distal tip of the probe, the flexible electrode terminal being extendable relative to the distal tip of the probe.

45. An electrosurgical system for applying electrical energy to a target site on a structure within or on a patient's body, the system comprising:

a high frequency power supply;

an electrosurgical probe comprising a shaft having a proximal end and a distal end, an electrode terminal disposed near the distal end, and a connector near the proximal end of the shaft electrically coupling the electrode terminal to the electrosurgical power supply;

a return electrode electrically coupled to the electrosurgical power supply; and

an electrically conducting fluid supply for directing electrically conducting fluid to the target site such that the electrically conducting fluid generates a current flow path between the return electrode and the electrode terminal.

46. An electrosurgical system as in claim 45, wherein the return electrode forms a portion of the shaft of the electrosurgical probe.

47. An electrosurgical system as in claim 46 further including an insulating member circumscribing the return electrode, the return electrode being sufficiently spaced from the electrode terminal to minimize direct contact between the return electrode and the patient's tissue.

48. An electrosurgical system as in claim 46, wherein the return electrode is an inner tubular member defining an axial lumen within the return electrode, the axial lumen having an inlet in communication with the electrically conducting fluid supply and an outlet in fluid communication with the electrode terminal.

49. An electrosurgical system as in claim 46, wherein the return electrode is an outer tubular member, the shaft further comprising an insulating member defining an axial passage between the insulating member and the return electrode, the axial passage having an inlet in communication with the electrically conducting fluid supply and an outlet in fluid and electrical communication with the electrode terminal.

50. An electrosurgical system as in claim 45 further including a fluid supply instrument separate from the electrosurgical probe, the return electrode forming a portion of the fluid supply instrument.

51. An electrosurgical system as in claim 50 wherein the return electrode is a tubular member defining an axial lumen therein, the axial lumen being electrically connected to the tubular member and having an inlet in communication with the fluid supply and an outlet for discharging the electrically conducting fluid towards the active electrode.

52. The electrosurgical system of claim 51 further comprising a plurality of current limiting elements each coupled to one of the electrode terminals for independent controlling current flow through the electrode terminals to inhibit power dissipation into the medium surrounding the target site.

53. An electrosurgical system as in claim 45 wherein the electrode terminal comprises an electrode array disposed near the distal end of the shaft, the array including a plurality

of electrically isolated electrode terminals disposed over a contact surface.

54. The electrosurgical system of claim 53 further comprising means for independently controlling power to the electrode terminals based on the electrical impedance between each of the electrode terminals and the return electrode.

55. The electrosurgical system of claim 45 wherein the electrode terminal comprises a single active electrode disposed near the distal end of the shaft.

56. The electrosurgical system of claim 45 wherein the target site is selected from the group consisting essentially of the abdominal cavity, thoracic cavity, knee, shoulder, hip, hand, foot, elbow, mouth, spine, ear, nose, throat, epidermis and dermis of the patient's body.

57. The electrosurgical system of claim 45 further comprising a current limiting element for controlling current flow through the electrode terminal to inhibit power dissipation into the medium surrounding the target site.

58. The electrosurgical system of claim 45 wherein the frequency of the voltage applied between the return electrode and the electrode terminal is in the range of about 20 kHz and 20 Mhz.

59. The electrosurgical system of claim 45 wherein the voltage applied between the electrode terminal and the return electrode is in the range from 10 volts (RMS) to 1000 volts (RMS).

60. The electrosurgical system of claim 45 further comprising means for controlling power to the electrode terminal based on the electrical impedance between the electrode terminal and the return electrode.

61. The electrosurgical system of claim 45 further comprising an insulating matrix surrounding and supporting

electrode terminal to electrically isolate a proximal portion of the electrode terminal from the electrically conducting fluid, the insulating matrix comprising an inorganic material.

62. The electrosurgical system of claim 45 wherein the inorganic material is selected from the group consisting essentially of ceramic, glass and glass/ceramic compositions.

63. An electrosurgical system for applying electrical energy to a target site on a structure within or on a patient's body, the system comprising:

a high frequency power supply;

an electrosurgical probe comprising a shaft having a proximal end and a distal end, an electrode terminal disposed near the distal end, and a connector near the proximal end of the shaft electrically coupling the electrode terminal to the electrosurgical power supply;

a return electrode electrically coupled to the electrosurgical power supply;

an electrically conducting fluid supply;

a fluid delivery element defining a fluid path electrically coupled to the electrode terminal for directing electrically conducting fluid to the target site and the electrode terminal to substantially surround the electrode terminal with electrically conducting fluid and to locate electrically conducting fluid between the electrode terminal and the target site.

64. The system of claim 63 wherein the return electrode is located on a surface of the patient's body.

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